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PRINCIPAL INVESTIGATOR: Kevin Cleary, Ph.D.

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13. ABSTRACT ***(Maximum 200 Words)***

This project is aimed at improving the state of the art of image-guided and minimally invasive spine procedures by developing a new generation of clinical techniques along with the computer-based hardware and software needed for their implementation. The current focus of the project is on physician assist systems incorporating robotics, tracking, and visualization to improve the precision of instrument placement and manipulation in minimally invasive procedures.

Key research accomplishments for this year are:

- Developed a protocol for applying a robotic needle driver to spine nerve blocks and received approval from the Army Human Subjects Board
- Demonstrated a robotic biopsy testbed incorporating robotics, tracking, and image overlay
- Developed a new technique for automatic registration of a vertebral body using an optical tracker and embedded fiducial carrier
- Our collaborators in the Urology Robotics Laboratory at Johns Hopkins Medical Institutions constructed the hardware for mounting the robotic needle driver on the computed tomography and fluoroscopy tables at Georgetown University Medical Center
- Established a new collaboration with the NSF sponsored Engineering Research Center for Computer Integrated Surgical Systems and Technology at Johns Hopkins University to develop a modular software architecture for physician assist systems incorporating robotics, tracking, and image guidance

14. SUBJECT TERMS

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3 Table of Contents

4 Introduction

This project is aimed at improving the state of the art of image-guided and minimally invasive spine procedures by developing a new generation of clinical techniques along with the computer-based hardware and software needed for their implementation. The current focus of the project is on physician assist systems incorporating robotics, tracking, and visualization to improve the precision of instrument placement and manipulation in minimally invasive procedures. The project is led by the Imaging Sciences and Information Systems (ISIS) Center of the Department of Radiology at Georgetown University and project collaborators include the Department of Radiology at Walter Reed Army Medical Center, the Urology Robotics Group at Johns Hopkins Medical Institutions, and the NSF sponsored Engineering Research Center for Computer Integrated Surgical Systems and Technology at Johns Hopkins University.

5 Report Body

This section describes the research accomplishments associated with each task in the statement of work. This is the second year report and includes research performed from 15 January 2000 to 31 December 2000. The award number is DAMD17-99-1-9022.

5.1 Task 1: Program Planning and Management

Program planning and management continues to focus on the direction of the project as well as relationships with project collaborators. Project planning and review meetings are held monthly at the ISIS Center, and it is the consensus that the current focus on physician assist systems for the next generation interventional suite is an appropriate direction.

To further leverage the research effort, a new partnership was formed during the past year with the NSF sponsored Engineering Research Center for Computer Integrated Surgical Systems and Technology at Johns Hopkins University. Through this project, the ISIS Center is supporting a graduate student at Johns Hopkins to develop software for a robotic biopsy testbed (see Task 3). Since there is no Engineering School at Georgetown University, this provides the project with a graduate student to help develop the algorithms and software for this testbed. It also allows us to leverage off the extensive medical robotics program at Johns Hopkins University.

Other management tasks have included the submission of quarterly reports to the Telemedicine and Advanced Technology Research Center (TATRC) at Fort Detrick.

5.2 Task 2: Robotics for Minimally Invasive Spine Procedures

One of the key accomplishments of this reporting period has been the development of a protocol for applying the "needle driver" robot from Johns Hopkins to minimally invasive spine procedures. This protocol was approved by the Georgetown Institutional Review Board in Spring 2000, and by the U.S. Army Human Subjects Board in Fall

2000. The protocol is attached in Section 10.4. A picture of the interventional suite where these spine procedures are carried out is shown in Figure 1[1].

The robotic hardware is being fabricated by the Urology Robotics Group at Johns Hopkins Medical Institutions. The concept is to mount the robot over the fluoroscopy and/or computed tomography (CT) table as shown in Figure 2. This concept is being realized in practice, as the robot frame has been completed along with mounts for the fluoroscopy and computed tomography tables at Georgetown (see Figure 3 and Figure 4). Finally, the complete robotic system has almost been finished as shown in Figure 5.

Once the system has been completed, the protocol mentioned above requires us to first complete a cadaver study. The robot will be mounted on the imaging equipment as shown in Figure 3 and Figure 4. The physician will then use the joystick to control the orientation of the robot as well as drive the needle into the spine. The initial clinical application will be nerve blocks, which requires the precise placement of a thin needle. The results of the cadaver study must be submitted to the Georgetown Institutional Review Board and Army Human Subjects Board before any human clinical trials can begin.

5.3 Task 3: Robotic Biopsy Testbed

In addition to the clinical protocol described in Task 2, we have also been developing a robotic biopsy testbed. The goals of this testbed are 1) to compare robotically assisted biopsy to the current practice and 2) serve as a testbed for investigating software architectures for integrating robotics, tracking, and visualization. A system diagram is shown in Figure 6.

The components of this system and the operational scenario are described in [Cleary 2001b][2], attached in the appendices. Briefly, the concept is that the physician will indicate on the CT scans the path for the biopsy as shown in Figure 7. This figure shows the CT scans of an interventional phantom along with the proposed biopsy path. The robot will then be used to follow this path. This requires an intermediate registration step as described in [Cleary 2001b] and shown on the poster [Cleary 2000e], which is also in the appendices. The registration method developed is explained later in this section.

A preliminary version of the system was completed over the summer of 2000, and demonstrated at the Medical Image Computing and Computer Assisted Interventions (MICCAI) conference in Pittsburgh in October 2000 (Figure 8 and Figure 9). The demonstration showed the ability of the robot to follow a pre-planned path on the CT images.

As part of this testbed, a novel method was developed for the automatic registration of a vertebral body using an optical tracker and embedded fiducial carrier. This method was tested on an interventional phantom (CIRS, Inc.) as shown in Figure 10. The fiducial

[1] All figures are in Section 10.1 which starts on page 14.
[2] All references are indicated by square brackets and listed in the reference section which starts on page 12. Copies of papers and posters are in the appendices.

carrier is manufactured by our tracking consultant, Neil Glossop, PhD, of Traxtal Technologies. The fiducial carrier contains 3 retro-reflective spheres (Figure 11) whose position can be tracked in real-time by the optical tracking system (hybrid Polaris, Northern Digital, Inc.). The fiducial carrier also contains 9 precisely spaced microspheres, which are small BBs approximately 1 mm in diameter (these cannot be seen in the figures). The microspheres appear as bright spot on the CT images and therefore their position in the CT coordinate system can be determined. Since we can also determine the position of the microspheres with respect to the optical tracking system (the microspheres are at known locations relative to the 3 retro-reflective spheres), we can use this information to establish a coordinate transformation between the CT coordinate system and the optical tracker. Since a fiducial carrier is also attached to the robot, we can use this information to command the robot to go to a desired point in CT space. Note that this can all be done without operator intervention, and this is a step to the fully automated biopsy systems of the future.

Current work has focused on the development of a modular software architecture for this testbed in cooperation with Johns Hopkins University. A paper on this concept is in preparation and will be submitted to the MICCAI 2001 conference.

5.4 Task 4: Investigate Tracking Component

Tracking, or the ability to locate an object in space, is an essential component of any image-guided surgery system. Most image-guided surgery systems use optical tracking technology (such as the Polaris™ from Northern Digital) and that is what we have adopted for our work. Optical tracker is accurate and robust, but suffers from the limitation that is line of sight. Therefore, it can be cumbersome in the interventional suite as the physician may interfere with the line of sight. In addition, optical tracking cannot be used to track fiducials internal to the body.

Other tracking technologies such as magnetic tracking do not suffer from this line of sight limitation, but until recently magnetic tracking has not been robust and reliable enough for interventional applications. However, Northern Digital has recently announced the Aurora™ magnetic tracking system (Figure 12), which is a tremendous improvement over earlier magnetic tracking technology, and has the potential for use in minimally invasive interventions. We have been working with our tracking consultant, Neil Glossop, PhD, of Traxtal Technologies to investigate the use of this system for interventional procedures. An SBIR proposal has been submitted to NIH to develop this concept (the evaluation of this proposal is pending but early reviews were extremely favorable) and we have been developing a demonstration of this technology for the Computer Aided Radiology and Surgery (CARS) 2001 conference in Berlin this June.

5.5 Task 5: Stereotactic Radiosurgery of the Spine

The goal of this task is to investigate new methods in localization (tracking) of the spine to enable precision delivery of a single dose of radiation, resolving the limitations of conventional radiation therapy. The plan is to use fiducials in or around the spine with modern treatment hardware capable of being directed in real-time using fiducial guidance. This is a partnership with the Departments of Radiation Medicine (James

Rodgers, PhD) and Neurosurgery (Fraser Henderson, MD) at Georgetown University Medical Center. Discussions were held with a commercial partner (BrainLab, Inc) and funds were set aside to purchase tracking equipment, but this task is currently on hold. This is because the Medical Center was purchased by MedStar Health this summer and the long-term strategy for Radiation Medicine and their research efforts is still under discussion. However, once this task gets underway, it is believed that the tracking techniques and expertise developed elsewhere in this project will be directly applicable.

5.6 Task 6: Minimally Invasive Body Interventional Procedures

This task is an outgrowth of our initial work in the spine to include body interventional procedures. The lead physician on this effort, Elliot Levy, MD, is particularly interested in the Transjugular Intrahepatic Portosystemic Shunt (TIPS) procedure and the use of image guidance [Levy 2000]. As part of this work, we have recruited a Radiology resident, Filip Banovac, MD, who has been assigned to the ISIS Center for one year. Dr. Banovac has been developing a medical phantom that will simulate the respiratory motion of the liver and be used to demonstrate magnetic tracking technology for targeting internal organs. The phantom is shown in Figure 13 and Figure 14. A commercially available medical phantom is being used as the base. The liver from this phantom will be mounted on a moving platform which is driven by a motor. The motor is controlled by a computer so that arbitrary motion patterns can be reproduced.

In a related development, Dr. Levy has been awarded a CIRREF Academic Transition grant (CIRREF is the Cardiovascular and Interventional Radiology Research and Education Foundation). This grant is to develop magnetic tracking technology for use in body interventional procedures in collaboration with Dr. Neil Glossop of Traxtal Technologies.

5.7 Task 7: Medical Simulation for Spine Procedures and Trauma Training

This task is a collaboration with the National Capital Area Medical Simulation Center of the Uniform Services University of the Health Sciences to develop simulation technology for military training. To date, a visiting researcher with a background in computer graphics has been hired and begun working part-time at the Simulation Center and part-time at the ISIS Center. One clinical application identified is needle thoracentesis, although other developments such as a low cost force feedback device for minimally invasive needle procedures are being investigated.

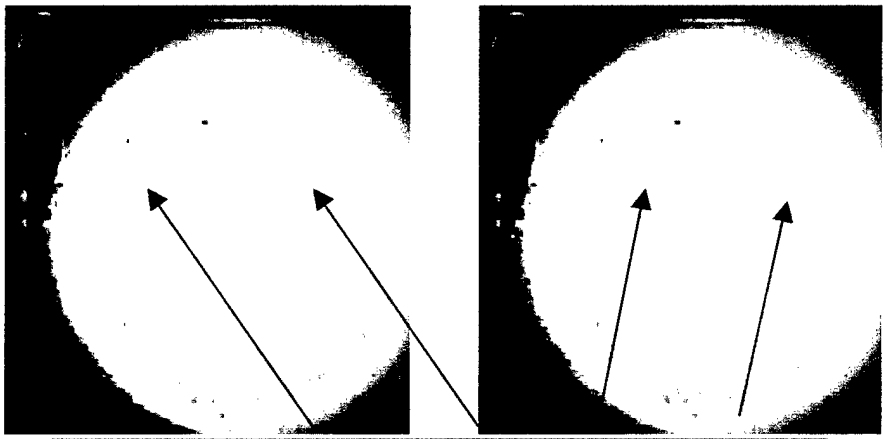
We plan to submit a proposal to develop this force feedback device to the National Medical Technology Testbed in Loma Linda, CA. Many surgical procedures involve the insertion of needles, guidewires, or catheters. While these procedures can be effectively taught using simulators, the development of simulation software is limited by the lack of a low-cost force feedback device. The goal here is to leverage technology developed by the gaming industry such as a force feedback joystick and adopt it for medical simulation.

5.8 Task 8: Ultrasound Imaging for Precision Guidance

In ultrasound imaging, projection ultrasound real-time tomography (PURTT) is a promising new imaging technology for high resolution imaging and precision guidance. Technology developments under consideration include detection of fragments of foreign materials in the soft tissues resulting from penetrating injuries, and guidance for minimally invasive procedures including: (a) catheter guidance, (b) needle guidance, and (c) guidance for vascular access. This is a collaboration with a local small business (Imperium Inc). A prototype wet device has been constructed that uses water as the transmission medium and a 128 by 128 detector array. Initial experiments of imaging of have shown promising results as elaborated below.

A series of experiments were conducted to define the imaging characteristics of PURTT using phantoms specifically designed for transmission ultrasound. The transducer operating at 5 MHz was used to measure the depth of field, contrast resolution using 5 mm and 3 mm phantom lesions, signal to noise ratio, attenuation dynamic range, gray level dynamic range and spatial resolution. Diagram 1 below shows the results obtained in one of these imaging characteristic experiments, the contrast resolution using phantoms mimicking calcification in breast tissue. In this experiment Zerdine™ with an attenuation value of 0.22dB dB/cm/MHz ±0.05db dB/cm/MHz was used as background material in the phantom as it approximates an average attenuation for breast tissue, and calcium carbonate beads with diameter ranging 150-850μm were used to mimic calcifications. Image artifacts around the lesions resulting from refraction phase contrast can be observed around the periphery of the lesions.

Diagram 1: Performance of contrast resolution on 3mm lesions



dB	0.06 dB	0.15 dB	0.5 dB	0.8 dB
Center	197	172	117	111
Background	153.4	149.8	153.9	147.0
Contrast	43.6	22.3	-36.9	-36.0
SD of background	12.5	11.3	10.9	9.9
SNR	3.49	1.97	-3.40	-3.62

In summary, using several customized phantoms, the imaging characteristics of PURTT operating at 5 MHz were investigated and the results of the performance of the ultrasound imager are the following:

1. The depth of field is 6mm.
2. The contrast resolution is <0.07dB for 3mm sphere.
3. The attenuation dynamic range is ~35dB.
4. The gray level dynamic range: 57 – 255 in 8-bit raw data.
5. The local noise level: 4 (at background) to 10 (at high intensity level).
6. The spatial resolution is ~300 microns.
7. Microcalcifications at ~300 microns are barely observable.

In the next year, we plan to continue the experiments and to seek additional funding for this work.

5.9 Year 3 Plans

The focus for year 3 and beyond is on physician assist systems incorporating robotics, tracking, and visualization for minimally invasive interventions. The robotic hardware will be delivered from Johns Hopkins and clinical trials should begin. The initial version of the robotic biopsy testbed should also be completed and a comparison study of robotically assisted biopsy to "standard" physician biopsy is planned. These studies should provide essential data for evaluating the place of these systems in the next generation of medical techniques. We will also continue to look for new funding opportunities and synergistic collaborations.

5.10 Walter Reed Collaboration

As part of this project, we are collaborating with Walter Reed Army Medical Center to investigate new clinical techniques and technological developments for spine procedures. The primary collaboration is with the Department of Radiology, under the direction of Col. Michael Brazaitis, MD, Chairman, and Irwin Feuerstein, MD, EBCT Radiologist. We have also been working with LTC David Polly, MD, of the Orthopaedic Surgery Service.

In the Department of Radiology, the focus of this collaboration this year has been the development of several proposals to use the unique imaging environment at Walter Reed to conduct several studies of interests to the active military and civilian population. A research associate from Georgetown has been stationed at Walter Reed to assist in this effort. Proposals that have been developed include:

1. Postmenopausal Coronary Artery Disease and Osteoporosis: Prospective Screening
2. An Evaluation of Statin Medication and EBCT for the Primary Prevention of Coronary Artery Disease
3. Screening for Environmentally-Induced Lung Cancer in an Exposed Military Population
4. Prevention of Musculoskeletal Injury and Osteoporosis in Active Duty Military Women Using Biochemical Markers and Bone Mineral Density

These proposals have been or will be submitted to various funding agencies, and it is hoped that this effort will provide a basis for future research at Walter Reed.

In the Orthopaedic Surgery Service, the FluoroNav™ fluoroscopy-based image-guided surgery system from Sofamor Danek has been purchased to provide image guidance in complex spinal cases. Dr. Polly has received IRB approval for a prospective recording of how long it takes to insert pedicle screws using FluoroNav. Four patients have been enrolled and data on 56 screws is available. The average fluoroscopy time with FluoroNav was 2.0 seconds per screw and the average time for screw insertion was 6.76 minutes. For conventional fluoroscopy guidance, fluoroscopy time per screw was 10.3 seconds and the average time for screw insertion was 7.1 minutes. Therefore, the preliminary results appear to indicate that FluoroNav will decrease fluoroscopy time. A CT scan analysis done to review accuracy of placement is in progress.

6 Key Research Outcomes

This section provides a bulleted list of key research accomplishments:

- Developed a protocol for applying a robotic needle driver to spine nerve blocks and received approval from the Army Human Subjects Board
- Demonstrated a robotic biopsy testbed incorporating robotics, tracking, and image overlay
- Developed a new technique for automatic registration of a vertebral body using an optical tracker and embedded fiducial carrier
- Our collaborators in the Urology Robotics Laboratory at Johns Hopkins Medical Institutions constructed the hardware for mounting the robotic needle driver on the computed tomography and fluoroscopy tables at Georgetown University Medical Center
- Established a new collaboration with the NSF sponsored Engineering Research Center for Computer Integrated Surgical Systems and Technology at Johns Hopkins University to develop a modular software architecture for physician assist systems incorporating robotics, tracking, and image guidance

7 Reportable Outcomes

This section provides a list of reportable outcomes. The major product of this year is the list of manuscripts given in Section 10, References. Six conference papers were published or submitted, eight poster presentations were made, and three journal articles were submitted. A protocol for robotically assisted nerve blocks was also approved. Copies of these documents are provided in the appendix.

In addition, two grant applications to the National Institutes of Health were submitted based on this work. A graduate student from Catholic University and a graduate student from Johns Hopkins University were supported during this year to assist in software

development for the robotic biopsy testbed. In a related development and outgrowth of this project, the Washington Area Computer Aided Surgery Society (www.washcas.org) was formed to promote research in the field.

8 Conclusions

The second year of work on the Periscopic Spine Surgery has continued to lay the groundwork for developing the physician assist systems of the future. These systems will incorporate robotics, tracking, and visualization to improve the precision of instrument placement and manipulation in minimally invasive procedures. A robotic biopsy testbed was demonstrated, along with a novel method for automatic registration. Investigations in new tracking techniques such as magnetic tracking were begun. The collaboration with Johns Hopkins was expanded to include not only the Urology Robotics Laboratory at Johns Hopkins Medical Institutions but also the Engineering Research Center at Johns Hopkins University. The robotic hardware from the Urology Robotics Laboratory will be delivered shortly and an IRB study for applying this hardware to spinal nerve blocks has been approved. These developments will continue in the next year with a focus on clinical feasibility and continued technology improvements.

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10 Appendices

10.1 Figures

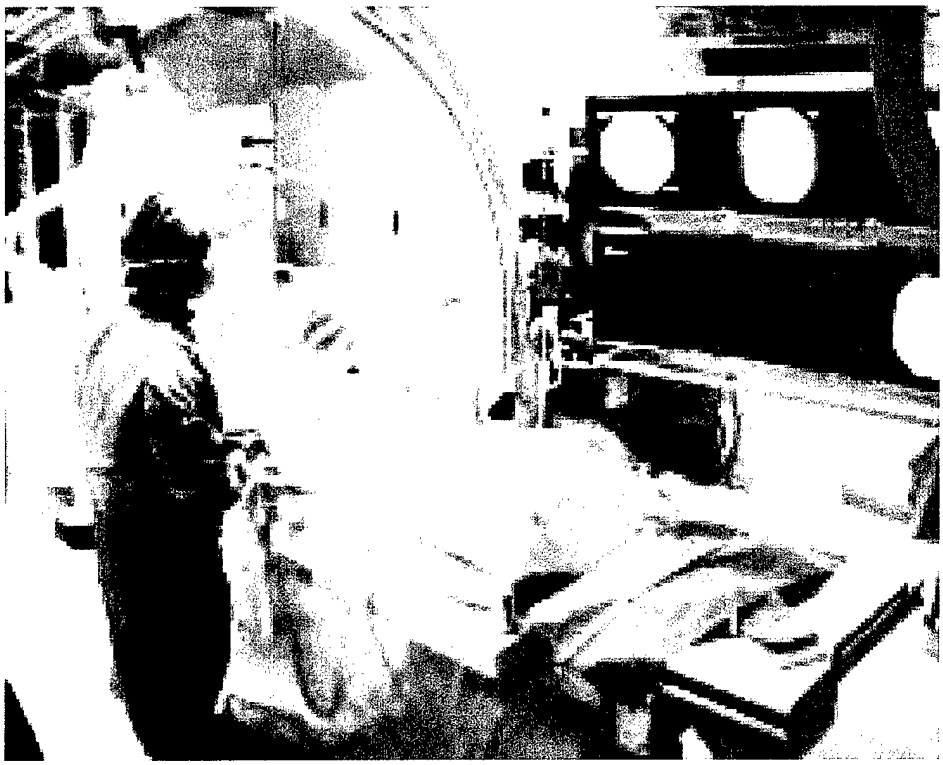

Figure 1: Interventional suite during typical minimally invasive spine procedure

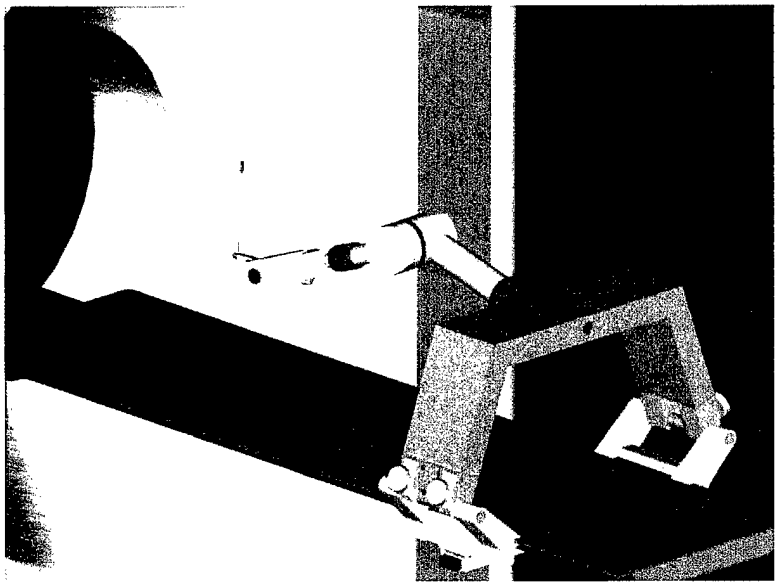

Figure 2: Concept for mounting of robot over patient table
(courtesy of Dan Stoianovici, PhD, Johns Hopkins Urology Robotics)

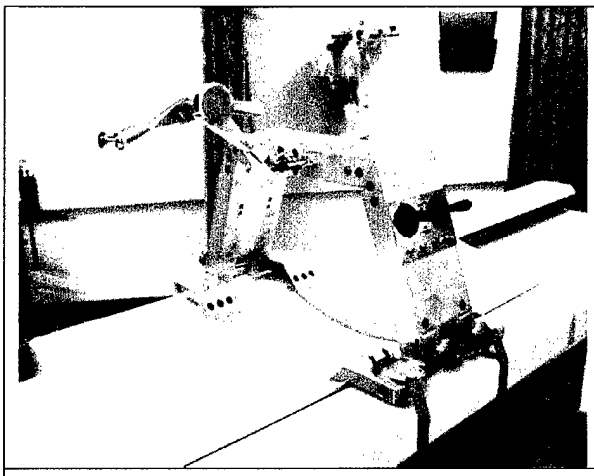

Figure 3: Robot arm hardware mounted on mobile CT table at Georgetown

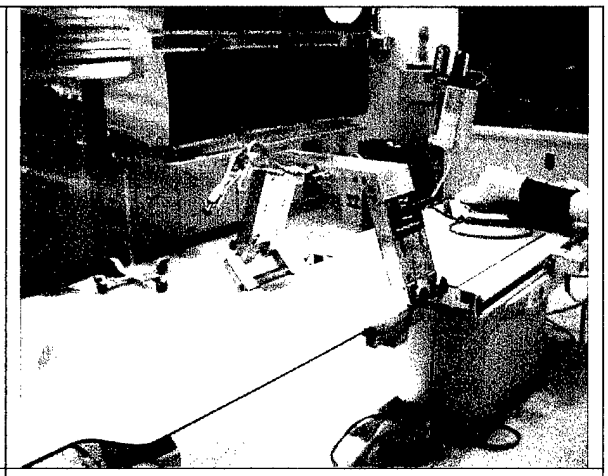

Figure 4: Robot arm hardware mounted on fluoroscopy table at Georgetown

(courtesy of Dan Stoianovici, PhD, Johns Hopkins Urology Robotics)

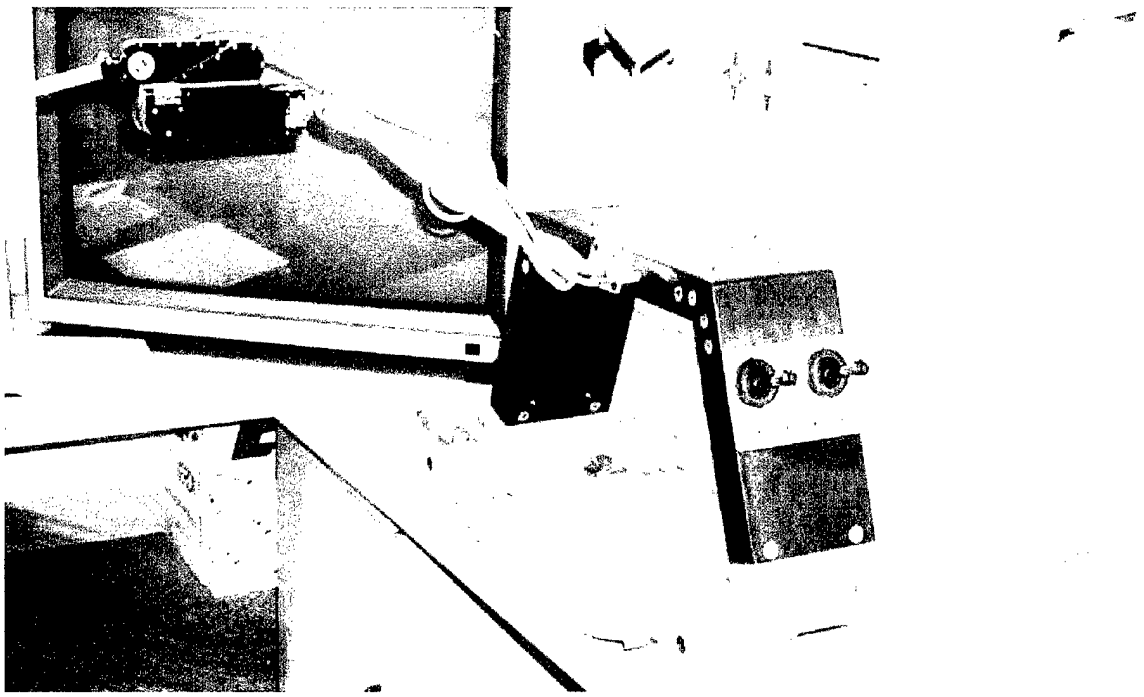

Figure 5: Complete robotic system with CT and fluoroscopy table mounts

(courtesy of Dan Stoianovici, PhD, Johns Hopkins Urology Robotics)

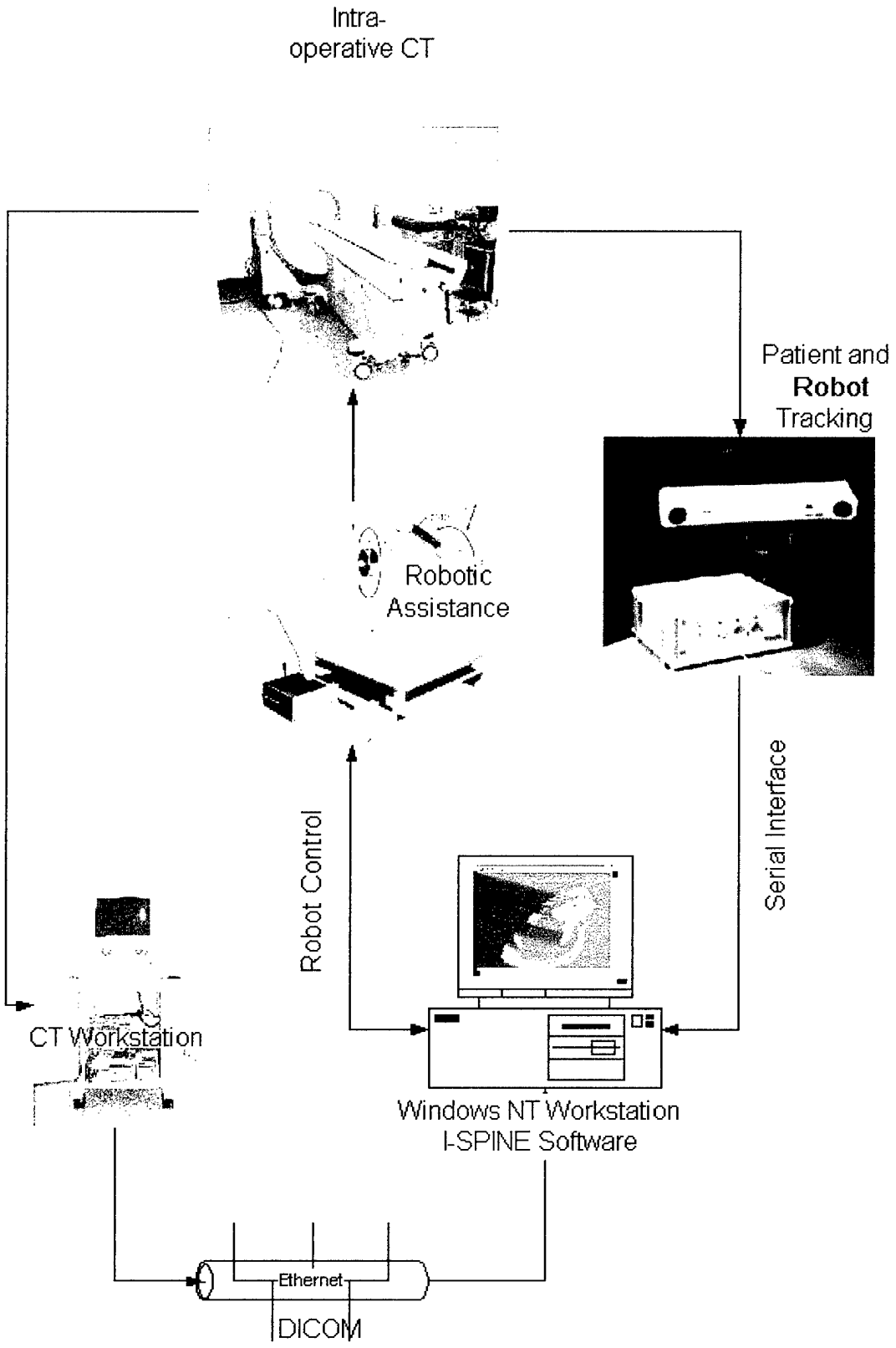

Figure 6: Robotic biopsy testbed architecture

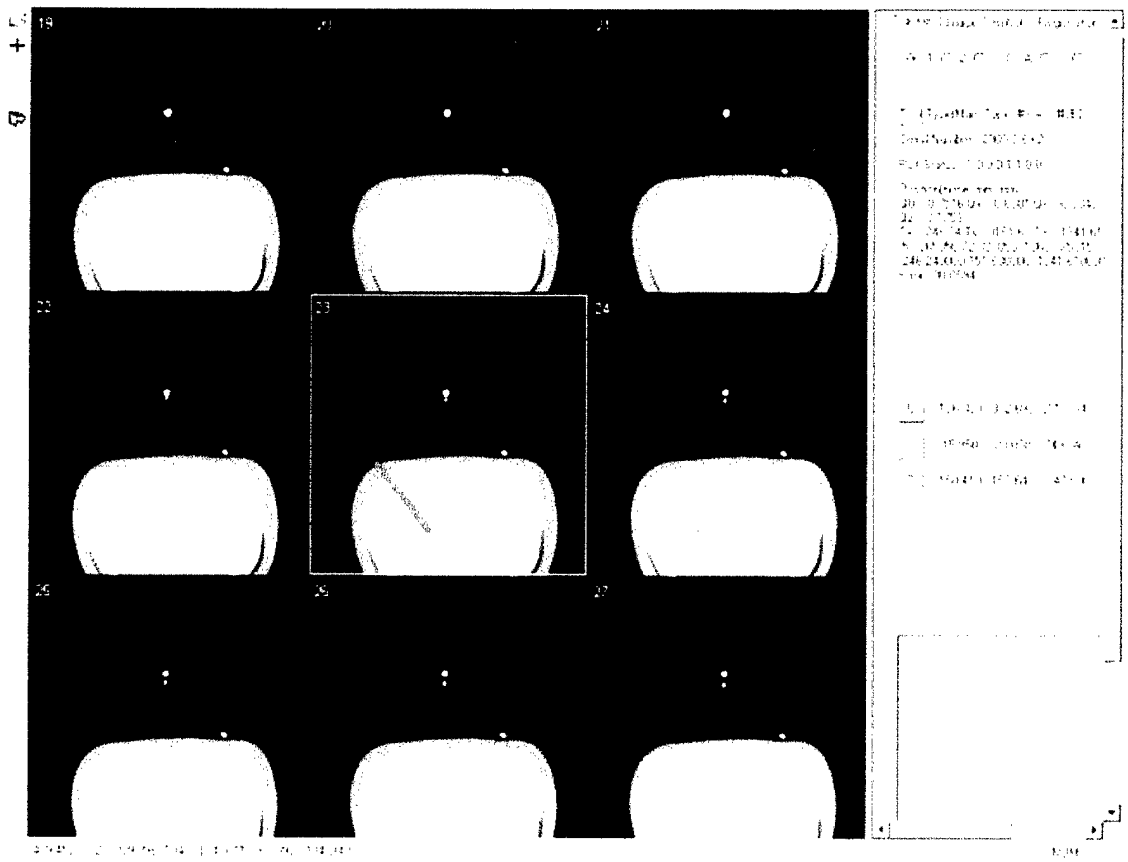

Figure 7: Robot biopsy testbed user interface
(CT scan of interventional phantom and proposed biopsy path shown)

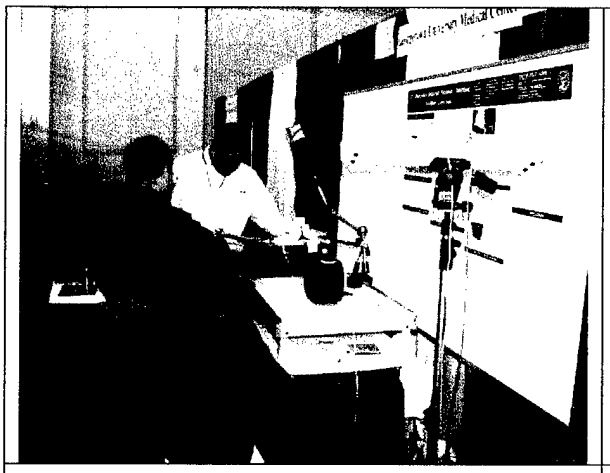

Figure 8: Demonstration of robot biopsy testbed components at MICCAI conference in Pittsburgh in October 2000

Figure 9: Close-up view of demonstration showing interventional phantom and probe being tracked

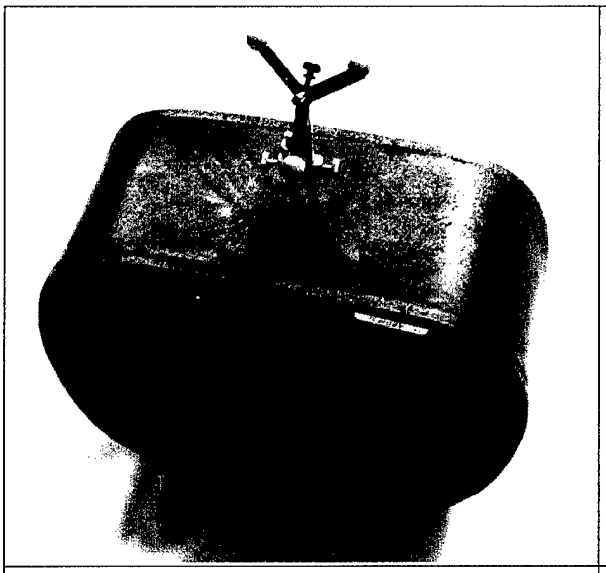

Figure 10: Interventional phantom with fiducial carrier attached to vertebral body

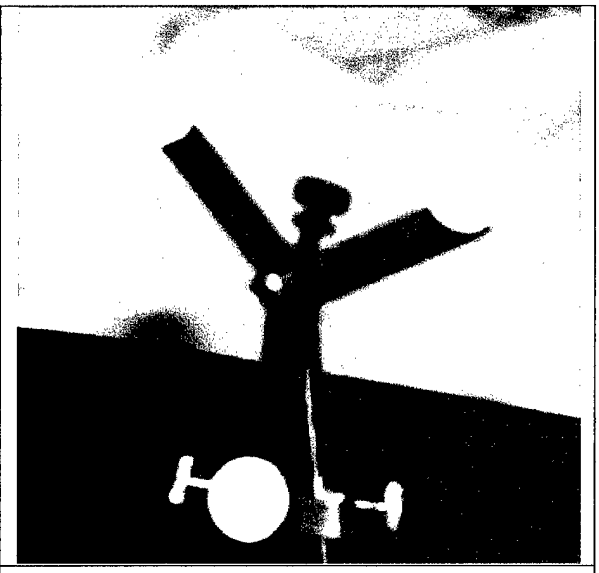

Figure 11: Close-up of fiducial carrier showing retro-reflective spheres

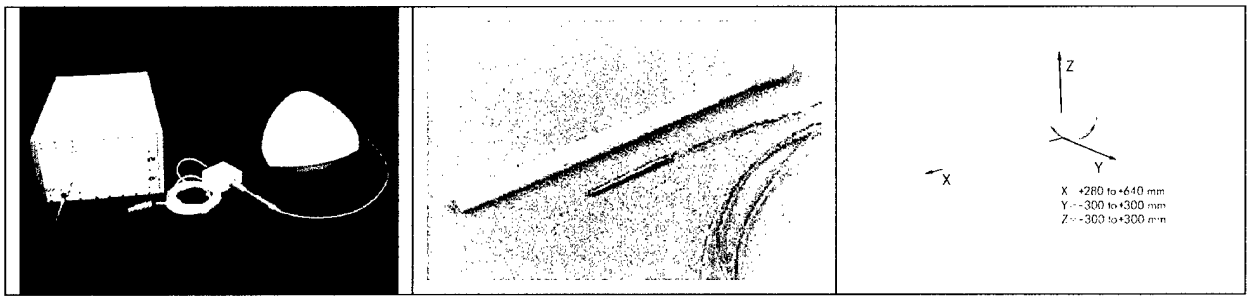

Figure 12: AURORA™ sensors, magnetic tracking system components, and measurement volume

The left picture shows (from left to right) the control unit, sensor interface device, and magnetic field generator. The middle picture shows the sensor coils along with the electrical wires protruding from the coil, compared to a match. The right picture shows the measurement volume in mm relative to the location of the field generator. (Photos courtesy of Northern Digital, Inc.)

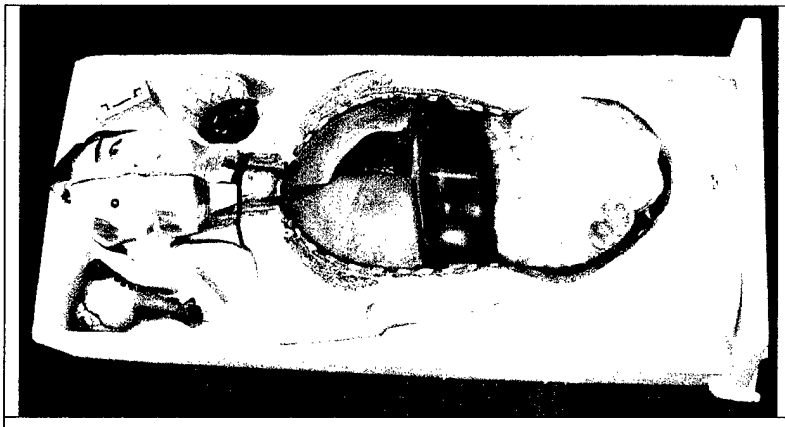

Figure 13: Medical phantom to be used in liver motion simulator (some organs will be removed and a skin surface will be stretched across the front)

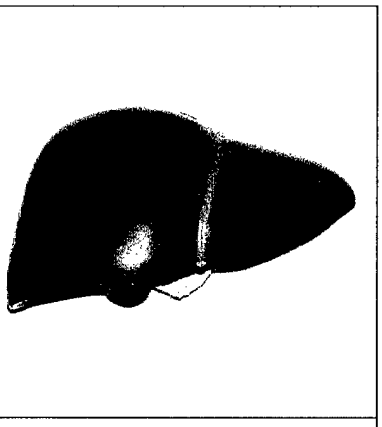

Figure 14: Liver from phantom (will be mounted on moving platform to simulate respiration)

10.2 Papers

Copies of the three journal papers submitted or published and six conference papers are reproduced in this section.

10.2.1 Alaoui 2000a: Development of a ...

Reprint begins on the next page and is 6 pages.

Presented at *Information Technology Applications in Biomedicine*,
November 2000

Development of a Secure Medical Research Environment

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Abstract

The confidentiality of medical information, including patient data security, is an increasingly important issue in today's health care environment. The Health Insurance Portability and Accountability Act of 1996 (HIPAA) [1] requires the Department of Health and Human Services to create specific rules for managing the security and privacy of computer-based patient medical records. In November 1999, the Department of Health and Human Services implemented the privacy requirements of the HIPAA proposal to improve the effectiveness of public and private health programs by protecting individually identifiable health information.

In this paper we will give a brief description of some widely used security measures. We will also address the steps that were taken at the Imaging Science and Information Systems (ISIS) Center at Georgetown University to secure our research environment and the patient medical information used within the network, and describe our efforts to become more HIPAA compliant. The paper concludes with some clinical applications.

Keywords: Firewall, Virtual Private Network (VPN), Security, Encryption, Medical

Significance

The Imaging Science and Information Systems (ISIS) Center, Department of Radiology, Georgetown University, conducts research in applications of advanced computing and telecommunications technology applied to healthcare. In its capacity as an important civilian research laboratory with many Department of Defense grants and contracts, the ISIS Center has established a reputation for technical sophistication and organizational effectiveness through projects such as DIN-PACS (Digital Imaging Network Picture Archiving and Communications—the prototype and technical specifications for the DOD filmless radiology system which was the groundwork for the military project known as MDIS (Medical Diagnostic Imaging System)), Project DEPRAD (Deployable Radiology—a digital imaging teleradiology network built in support of the US troops in Bosnia-Herzegovina), and digital mammography (a proof of concept project and working model of adapting computed radiography technology to digital mammography). The ISIS Center also successfully competes for extramural funding from other government agencies including the National Institutes of Health and the National Science Foundation in the areas of image processing, computer-aided diagnosis, telemedicine, and image-guided therapy.

The ISIS Center faces major changes in its research environment. On the one hand, many projects acquire, manipulate and archive patient identifiable information on the ISIS Center local area network (LAN). This includes data from clinical trials for government and commercial funding agencies that are subject to Food and Drug Administration rules and regulations. On the other hand, investigators, physicians, and patients increasingly require remote access to such data using dial-up and web-based technologies. Whereas the ISIS Center has not historically faced major data security problems in its connections with untrusted networks, remote access requirements led to the development of a plan for managing the security and confidentiality of patient identifiable information on its LAN. The ISIS Center's approach to data security functions to protect patient data and to demonstrate how research involving patient data may be accomplished in a secure environment.

Primer on Security Options

Levels of Security

As in all academic, research, and commercial sectors, the Internet has become a vital mechanism in healthcare. Within the healthcare community, many physicians, researchers, and patients use the Internet to gather medical information. In addition, more and more patients are gaining access to their clinical data over the Internet. However, with increased ease of use and access to confidential information comes increased threats and vulnerabilities. Some of the threats that are of concern to healthcare professionals include unauthorized access, hacker attacks, virus infections, e-mail spamming, and address spoofing.

To address these risks there are a number of solutions and techniques that can be applied. The next section will discuss some of the more popular techniques available to secure a network and its data from the above-mentioned risks and threats.

Firewalls

A firewall [2] is a first line of defense against unauthorized attacks on the network. It controls access to a trusted network from outside users while allowing inside users access to the Internet and the outside world. It forces all connections to and from the untrusted network to pass through and obey all policies set at the firewall. A good firewall will achieve a delicate balance between desirable and undesirable data accessibility. A firewall can operate at different Open Systems Interface (OSI) layers and can be configured with multiple proxies to minimize compromising the users inside the firewall while remaining transparent. There are three types of firewalls:

1. Packet filter gateways are firewalls that operate at the lower level of the OSI model. A packet filter only checks for destination IP addresses and port numbers before granting access to the trusted network.
2. Circuit-level gateways are like packet filters except that they operate at a different level of the OSI protocol stack. Unlike most packet filters, connections passing through a circuit-level gateway appear to the remote machine as if they originated from the firewall. This is very useful for hiding information about protected networks.
3. Application level gateways are the most secure of the three firewall types mentioned here. Application level gateways function at the highest level of the OSI model, the application layer. These systems support strong user authentication and are data and application aware.

Acquiring and installing a firewall is just one piece of the security puzzle. Besides firewalls there are different security measures that can minimize threats and vulnerabilities. These other measures will now be discussed.

PKI

Public Key Infrastructure uses a pair of "keys"—public and private—to encrypt and decrypt messages. All messages and data sent using PKI are encrypted. The messages can only be decrypted by using the private key.

The two "keys" in a key pair use a sophisticated mathematical algorithm. When one key performs a certain function (such as encrypting an electronic message), only its corresponding key can complement that function (and decrypt the message) and in the process authenticate the sender and the integrity of the message.

In public key cryptography (the process that PKI supports), a key pair is used to encrypt and decrypt messages sent electronically over unsecured paths. It is this mathematical relationship that gives public key cryptography its power to provide for confidentiality, authentication, data integrity, and for access control for open highly scalable applications such as those needed and used in healthcare applications.

Access Controls and Authentication

Other than the basic login name and password combinations, there are different authentication methods used to increase security and access control to a network. Organizations can select one or more methods of authentication, most suitable for their applications. One of the most popular authentication methods is SecureID because it provides strong authentication and does not requires special readers or hardware. It uses a "token" to access the system. Other emerging authentication methods include Biometrics readers such as fingerprint readers, iris scanners, facial imaging devices, hand geometry

readers, and voice readers. These provide an extra level of security and access control.

Virtual Private Networks

Virtual Private Networks (VPNs) are an emerging technology. They provide reliable low cost protection and privacy for organizations compared to the use of leased lines. All messages and data transferred over a VPN are encrypted.

A VPN creates a secure environment to access the Internet and exchange information and data. VPNs can be deployed to protect two networks or single workstations connected a secured network. With a VPN, remote users get connected to the trusted network as if they were on the same network. The Internet Key Exchange protocol (IKE) is used to authenticate, negotiate and manage the encrypted traffic.

ISIS Center Firewall

Steps Toward Security

In order for the ISIS Center to establish a secure network, the acquisition and implementation of a firewall started in 1998. A risk and needs assessment was undertaken to identify the potential risks to the network and weigh them against the threats of attack, loss of data, etc. Questionnaires were circulated to all researchers to determine the systems and communications/network protocols used within the ISIS Center and at remote sites that collaborate with the ISIS Center. All this information led to the creation of a comprehensive request for proposal (RFP). Vendors were asked to respond to specific user questions as well as being told what the expectations were of the vendor and/or firewall product.

All ISIS Staff evaluated vendor responses independently, and SecureMethods, Inc. (formally DynCorp) was selected to install and configure a Gauntlet firewall. SecureMethods worked with ISIS Center personnel to define security protocols and determine the appropriate firewall configuration. It was important to coordinate with and keep all ISIS staff members informed as the firewall could potentially impact their use of network services. Finally, installation and testing was scheduled over a weekend. During this time, access to the Internet and the outside world was limited.

Multiple system tests were performed to validate the configuration and operation of the firewall. Changes were made when user expectations were not met or when important tasks could not be carried out because of firewall settings. Each project was analyzed and tested to ensure that a mechanism was in place to allow the project to continue to operate with the firewall installed. The maintenance of the firewall and modification to the configuration is an ongoing task.

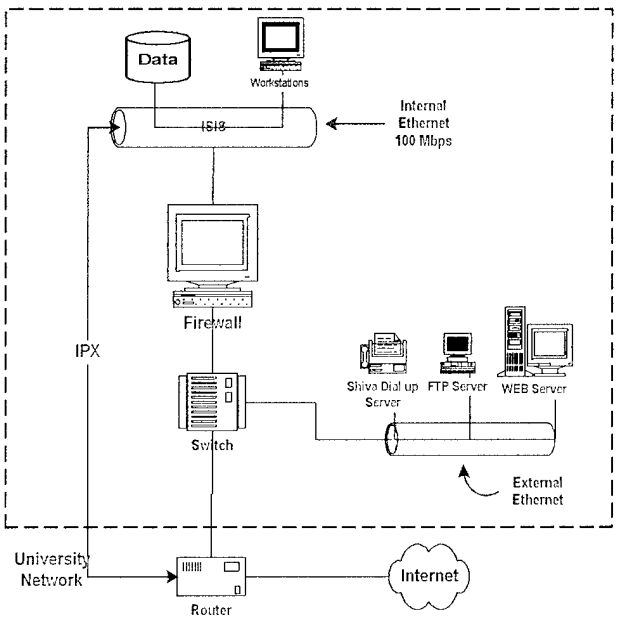

Figure 1. ISIS System Architecture

System Architecture

The major components of the ISIS network are shown in Figure 1 and include the Gauntlet firewall, a Cisco switch, and a router. The Gauntlet version 4.2 firewall is installed on a Micron PC running the Unix BSD 3.1 operating system with 128 MB RAM and a 10 gigabyte hard drive. The PC has 2 network cards: one connected to the outside untrusted network and the other connected to the ISIS LAN (trusted network).

As shown in the diagram the Cisco switch (Catalyst 5509) separates the ISIS network into two segments: internal (trusted) and external (untrusted). The Cisco

switch also provides 100 megabits per second (Mbps) internal network speed.

All access to the ISIS network is through the firewall, except for the IPX protocol (Novell Protocol) which is routed around the firewall. IPX is not supported by the firewall and is considered a minimal security risk. To remotely access the internal network, registered users are authenticated by the firewall using a password generated by remote authentication software on the user's computer. Patient identifiable data, an email server, and data not meant for the general public are stored inside the trusted network. Our Web server, FTP server, and Shiva dial-up server are on the external Ethernet.

Gauntlet Firewall

The Gauntlet Firewall is a hybrid firewall operating as an application gateway and as a circuit gateway. Table 1 lists some of the important application proxies to the ISIS Center.

Proxy	Authentication	Extras
HTTP	Yes	Active X, Java, URL Filtering, Cyber Patrol
SSL	No	
SMTP	Yes	Virus Scan, Limit Size, Anti-Relay, Anti-Spam
POP3	Yes	
FTP	Yes	Transparent, Content Scanning
SQL	No	
Netmeeting	No	
Plug Proxy	No	Can be customized and configured to any port

Table 1. Gauntlet Proxies used at the ISIS Center

One limitation we found with the firewall is the lack of commercially available DICOM or IPX proxies. At the time of selection of the Gauntlet, there were no commercially available firewalls that contained these proxies. Both of these are important messaging protocols used within our environment.

To work around these limitations, a "secure hole" is opened in the firewall using a packet screening mechanism that allows communication between two known computers for known protocols and port numbers. A plug proxy can also be configured for any application allowing transport through a defined port. While the packet screening mechanism and plug proxy worked well for the DICOM protocol, IPX data still has to be routed around the firewall.

Management

The Gauntlet Firewall manager is the primary tool used for managing the firewall. It has a secure graphical interface accessible from authorized computers on the trusted network and allows remote workstations access to the firewall configuration.

Since the firewall administrator needs to be constantly aware of possible attacks, the reporting capabilities of Gauntlet are very useful, helpful and informative in this aspect. The firewall reporting and alerting features [3] are customizable and configurable to provide:

- Frequency Reports
- Types of Alerts
- Message Log
- Email Alerts

The reporting module of the Gauntlet also allows for logging and monitoring all failed processes, failed access attempts, packets that failed to pass the filter, and activities contrary to firewall configuration. Figure 2 shows an email message automatically sent from the firewall to the administrator warning of possible security violations.

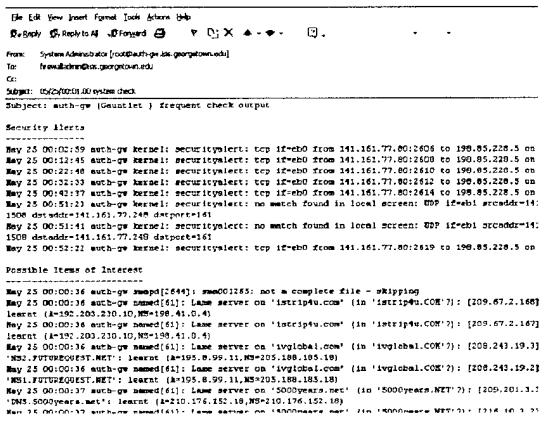

Figure 2. Firewall Alert Email Example

Clinical Applications

With the firewall in place and configured to ISIS Center specifications and policies, we are able to securely use our systems to acquire and store not only research data but also patient information. Some examples of clinical applications at the ISIS Center that require secure data transfer are described below.

MyCareTeam

This is an interactive Web Site developed at the ISIS Center to give patients with diabetes and kidney disease access to their daily clinical data and to securely communicate and exchange medical information with their healthcare team. Diabetes patients connect to a secure Web site over the Internet using encryption and upload their daily blood glucose readings to the database which sits behind the firewall.

For patients with kidney disease, a point-to-point modem connection is established between the Peritoneal Dialysis (PD) machine in the patient's home and a secure database application at the ISIS Center. The data is securely uploaded to the database through the Web application. The patients can then access their daily PD data from the Web site. In designing the site, the HIPAA requirements for ensuring the protection of the privacy of medical information were taken into account [4].

To provide secure access to the data, the firewall was configured to allow traffic between the Web server (external Ethernet in Figure 1) and the Database server within the trusted Network (internal Ethernet in Figure 1). A Secure Socket Layer (SSL) connection is established with all pages in the Web site that transfer confidential data. 128-bit encryption is used.

Multi-Center Clinical Trial

A digital network for transferring magnetic resonance images (MRI) between multiple clinical institutions, the ISIS Center, and the Kennedy Krieger Institute in Baltimore, Maryland is under development under a National Library of Medicine contract. The purpose of the network is to develop a database of patients with a rare neurological disorder called ALD or Adrenoleukodystrophy. The purpose of the network is to facilitate clinical trials of new therapies or treatments. The secure transmission and storage of the MRI data is required.

While the firewall protects the data that sits behind it, other mechanisms were implemented to ensure no loss of data, no unauthorized access to the data, and to preserve the confidentiality of the patient data. First, VPNs are established between contributing clinical sites and the central database whenever possible. VPN client software is provided to contributing sites if a VPN server is not available at their institution. Similarly, patient names and unique identifiers are masked as soon as the data enters the database. This not only preserves the confidentiality of the patient data, but also blinds the researchers to the therapy the patient may be on when evaluating their MRI. Finally, the DICOM standard requires that the contributing site be known to the receiving system before the receiving system will accept its data. Similarly, sites that query the DICOM database, must be known and approved within the DICOM Query/Retrieve server before data are sent out.

Visualization

As part of a project in computer aided surgery, the ISIS Center often has a need to exchange DICOM images with clinical departments at the hospital or other research groups. One example of this need is related to our work with the Interventional Radiology group at Georgetown University Medical Center. We provide engineering support and systems integration assistance for a mobile CT scanner. The scanner is used during interventional radiography cases to obtain a series of axial images, which can then be reconstructed into a three-dimensional display for visualization purposes. Since the engineers working on this project are situated at our research group, we need to transfer the CT images from the hospital to the ISIS Center located 1 mile away. This image transfer is done using the DICOM protocol, and requires appropriately configuring the firewall as discussed earlier.

Conclusion

Now that the firewall has been installed, ISIS Center network administrators are able to restrict access to the internal network, monitor all transactions to and from the local area network, and securely exchange patient information and images with different institutions using the Internet. While changes to

existing network architecture and operating environment were required, the transition to a secure environment went relatively smoothly. Participation and cooperation by all group members was critical towards minimizing inconveniences. The costs associated with the firewall implementation are moderate, but some dedication by the network administrator is required. We anticipate that such systems will become more common in the medical field as requirements for secure medical data become more widespread.

Acknowledgements

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The authors would like to thank Albert Green Jr., Jeffrey Collmann, Ph.D., and Marion Meissner, MS, for their contributions to this article and the firewall installation.

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10.2.2 Choi 2000: Efficient volumetric ray casting ...

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Efficient Volumetric Ray Casting for Isosurface Rendering

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Abstract

While volume rendering is becoming more widely used in medical applications, it is still difficult to generate a good quality image interactively without expensive hardware when the size of the dataset is quite large. For interactive rendering of a large dataset, we present an acceleration method, image-space bounding surface. Using an image-space bounding surface, the isosurface ray casting is accelerated by avoiding unnecessary volume traversals. Image-space bounding surface can be interactively handled by polygon rendering hardware even in a conventional personal computer. Two optimization techniques, LF-minmax map and memory bricking, are also employed to efficiently render isosurfaces. This paper also shows that the algorithm can be extended to multiple isosurfaces rendering. The experimental results show that the algorithm generates a good quality image of a large dataset interactively on a standard PC platform.

Keywords : volume rendering, isosurface ray casting, polygon rendering hardware, image-space bounding surface

1. Introduction

Many medical applications generate scalar fields from imaging devices such as computed tomography (CT) or magnetic resonance imaging (MR). The scalar fields can be visualized by volume rendering algorithms that can be categorized into surface rendering and direct volume rendering techniques. While surface rendering displays isosurfaces in the volume, direct volume rendering visualizes a volume according to an opacity transfer function. Regardless of the volume rendering technique, it is difficult to produce a good quality image without expensive hardware such as multi-processor workstations. In this paper, we present an efficient isosurface ray casting method for a large dataset with inexpensive hardware.

Polygon-based rendering approaches [6, 16] such as Marching Cubes are the most common methods in surface rendering. They generate polygons that approximate isosurfaces from a volume. The extracted polygons are rendered by a polygon rendering algorithm. Even if polygon-based rendering is usually faster than volumetric ray casting, it has some problems. First, it takes a lot of time to change the isosurface of interest in polygon-based rendering, which makes it difficult to do this in real time. Second, for a large dataset, polygon-based rendering generates a huge amount of polygons that cannot be easily managed even on a high-end graphics workstation. Third, it is not straightforward to visualize a cutting plane or the interior of the volume in polygon-based rendering.

Ray casting [2,3,4,13], the most frequently used algorithm in direct volume rendering, has also been used for displaying isosurfaces [5,8,14]. Isosurface ray casting[1] generates rays from a viewpoint through each screen pixel into volume space, and it finds the intersection point of the ray and the isosurface. The intersection point can be found by an analytic method [5] or an interpolation method [14]. The intensity value of the pixel is calculated at the intersection point.

In isosurface ray casting, traversal operations consume the most time. Several techniques have been used

for efficient traversal. Hierarchical data structures such as octrees [2,8] or K-d trees [12] can be used to skip over empty regions by using a macrocell that contains the minimum and maximum value for its children nodes. Using macrocells, the ray/surface intersection test can be simplified by comparing the isosurface value with the minimum and maximum value.

A distance volume that contains the distance to the nearest possibly contributing cell has also been developed [11,17]. In these methods, a significant amount of additional memory is required to store the distance values, and building the distance volume can make it difficult to interactively modify the isosurface.

The presence-accelerated ray casting [15] estimates a highly accurate object presence by projecting all grid cells associated with the object boundary onto the image plane without using polygon rendering hardware. This technique requires a preprocessing stage to generate a classified volume, which makes it difficult to change the isosurface of interest. Even if an interactive classification is provided, the performance of the algorithm is degraded.

The PARC (Polygon Assisted Ray Casting) algorithm [1,10] estimates the surface location using polygon rendering hardware. An approximation of the isosurfaces is projected into image-space, and the information from the Z-buffer is used to identify segments of the ray that could possibly contribute to the final image. For the approximation of the isosurfaces in the PARC algorithm, a bounding surface is created in volume space. Even if the rendering time of the PARC algorithm is reduced greatly, too many polygons are generated when the size of the dataset is quite large such as the Visible Human dataset [7]. A hierarchical volume can be employed to reduce the number of polygons to be interactively handled by polygon rendering hardware, but ray casting performance is degraded because the number of cells to be processed increases.

This paper presents an efficient isosurface ray casting method for a large dataset. We propose an acceleration technique using an image-space bounding surface for interactive rendering. Using an image-space bounding surface, the performance of isosurface ray casting can be greatly enhanced. Since the

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[1] In the remainder of this paper, we define isosurface ray casting as ray casting for isosurfaces.

number of polygons in an image-space bounding surface is not affected by the size of dataset, it is possible to render a large dataset interactively. For fast searching of isosurfaces, two optimization techniques, LF-minmax map and memory bricking, are also employed. The experimental results show that the new algorithm provides interactive performance for a large dataset on a standard PC platform as well as on a high-end graphics workstation.

In Section 2, the basic algorithm of isosurface ray casting is explained. In Section 3, an image-space bounding surface is presented. Section 4 describes two optimization techniques, LF-minmax map and memory bricking. In Section 5, the isosurface ray casting algorithm is extended to render multiple isosurfaces. In Section 6, some rendering results and computation times are shown. Finally, conclusions and suggestions for future work are given.

2. Ray Casting for Isosurface Display

In this section, we explain the ray casting method for isosurface display. Assume that each voxel represents the density of material at a point and an isosurface value is a certain density value. From the intersection between the ray and the bounding box of the volume, voxels are sampled at regular intervals. The condition that an isosurface lies in the interval $[t_i, t_{i+s}]$ is :

$$D(t_i) \le d_{iso} \le D(t_{i+s}) \quad \text{or}$$

$$D(t_{i+s}) \le d_{iso} \le D(t_i)$$

where

t_i : distance from the viewpoint to the point i

$D(t_i)$: density value at t_i

d_{iso} : isosurface density value

s : sampling distance

When the above condition is satisfied, there exists t_{iso} in $[t_i, t_{i+s}]$, which meets the following condition since the trilinear interpolation function is continuous.

Condition : $D(t_{iso}) = d_{iso}, t_i \le t_{iso} \le t_{i+s}$

Several methods have been devised to find t_{iso}, one of which is the analytic method. The analytic method [5] models the isosurface as an analytic function, and the intersection between a ray and the isosurface is computed directly from the function. In the interpolation method, the isosurface can be found by interpolation of the surface location between successive sample points. The interpolation method generates a better image than the analytic method (Figure 1) because the interpolation method continuously searches the exact isosurface in the cell instead of estimating the surface location from the analytic function.

3. Accelerated Ray Casting Using Image-Space Bounding Surface

In isosurface ray casting, traversal operations consume the most time. The performance can be enhanced if we reduce the number of traversals. A set of surfaces, called a bounding surface, which contain all the possibly contributing cells is used to reduce the number of traversal operations. For example, in Figure 2, only the thick lines in Figure 2(b) need to be traversed instead of all the thick lines in Figure 2(a).

The PARC algorithm [10] generates a bounding surface in volume space. While the PARC algorithm generates a bounding surface in volume space, our method constructs a bounding surface in image space. It is called an image-space bounding surface, and it has the following advantages. First, its rendering time is proportional to the image size not the volume size. Second, all the possibly contributing pixels can be anticipated, which avoids generating unnecessary rays.

A flowchart of our method is shown in Figure 3. At the initialization step, the isosurface ray casting algorithm without a bounding surface must be run to generate depth values which are necessary for

constructing an image-space bounding surface. During the isosurface ray casting, the depth value, the distance from the viewpoint to the isosurface, is saved for each pixel. If a ray does not intersect with the isosurface, the distance from the viewpoint to the far plane of the volume is saved for the pixel.

Once a depth buffer is generated from the isosurface ray casting, an image-space bounding surface can be constructed. Figure 4(a) and (b) show how to construct an image-space bounding surface. The rectangle representing a pixel is added into the image-space bounding surface as depicted in Figure 4(a). To fill the gap between pixels from the depth difference, rectangles connecting two pixels are added into the image-space bounding surface as shown in Figure 4(b). Figure 4(c) and (d) show example images of an initial image-space bounding surface and a rotated image-space bounding surface.

After constructing a bounding surface, it is sent to the polygon rendering hardware. In the rendering process, depth values are saved for each pixel in the Z-buffer. With the depth values, isosurface intersection calculations are performed on a cell-by-cell basis along the ray as described in Section 2. The image-space bounding surface must be reconstructed whenever the viewpoint or the isosurface of interest is changed.

When the number of polygons in the image-space bounding surface becomes large, the bounding surface can be constructed in lower resolution. However, there are some trade-offs between the polygon rendering time and isosurface ray casting time according to the resolution of the bounding surface. As the bounding surface is generated in higher resolution, the isosurface ray casting becomes more efficient because more accurate skipping tests are possible. However, a higher resolution bounding surface requires more polygon rendering time.

Current personal computers as well as high-end graphics workstations have the ability to render a number of polygons. Polygon rendering hardware can accelerate the estimation of isosurface locations, which can enhance the rendering performance greatly.

4. Further Optimization for Interactive Isosurface Rendering

Even if an image-space bounding surface approximates surface locations well, the algorithm has to

traverse many empty cells. In order to traverse empty cells efficiently, two other optimizations are employed in our implementation.

Some algorithms used a hierarchical data structure such as an octree to traverse the volume efficiently [2]. However, an octree requires a complex operation to advance along the ray. We use an LF (Loose-Fitting) minmax map[2] to simplify the ray sampling.

In a traditional octree, the intersection points **a, b, c, d** in Figure 5(a) have to be checked to find the nodes I, II, III that may contribute to the ray. In the LF-minmax map, the nodes are checked with equal spacing as shown by points **a, b, c** in Figure 5(b). In this case, it is possible to miss the part of the line labeled **i** in Figure 5(b) and corresponding to the line between points **b** and **c** in Figure 5(a). This can result in an inaccurate skipping test. To solve this problem, we expand each node in the LF-minmax map to cover a larger area than the original area. The function to compute an intermediate level node is $f(x,y,z)=n_{\lfloor x/m\rfloor\lfloor y/m\rfloor\lfloor z/m\rfloor}$ where the sampling point is (x, y, z) and the size of the intermediate level is $m\times m\times m$. The node $n_{i,j,k}$ saves the minimum and maximum value in the region of [$mi-\beta, mi+m+\beta$], [$mj-\beta, mj+m+\beta$], [$mk-\beta, mk+m+\beta$]. Using a larger β value prevents the ray from missing the interval **bc** in Figure 5(a). The shaded part in Figure 5(d) represents the part that can cause a problem when the sampling distance and node size are the same.

The larger the value of β, the less chance the sample will be missed, but the more chance the skipping test will fail. Therefore, the smallest β that does not miss the sample should be chosen. When the node size is 1 and the sampling distance is 1, the best value of β is $\frac{1}{2\sqrt{2}}$ as shown in Figure 5(d).

When an LF-minmax map is used as an intermediate level of the hierarchical structure for the skipping test, the skipping test is performed using the sampling distance of the intermediate level. If the skipping test fails, the level of the LF-minmax map is decreased. Assume that the size of a node is $m\times m\times m$ and the sampling distance is m. If the skipping test fails at the sampling point t, the interval that may include the

isosurface is [t-m, t+m]. Therefore, the algorithm checks the minmax map in the lower level and resumes at the t+m point.

Another optimization technique used in our implementation is memory bricking [8]. Current CPUs employ high-speed cache memory between the main memory and processor to improve performance. In the isosurface ray casting as well as ray casting, the voxel data is referenced often. By repositioning the voxel data within the memory, the performance of the algorithm is increased because of the spatial coherence.

5. Multiple Isosurfaces Rendering

In this section, we extend the isosurface ray casting algorithm to render multiple isosurfaces. In the case of m isosurfaces, a list of isosurfaces can be defined as follows :

ρ_0 : minimum density value

$\rho_1, \ldots, \rho_m$: sorted list of density values of isosurfaces in increasing order

ρ_{m+1} : maximum density value

A level of the ray is defined l if the density value of the current sample point is between ρ_l and ρ_{l+1}. Along the ray, for a sampled position of the ray t_i and at a level l, $D(t_i)$ satisfies :

$$\rho_l \le D(t_i) \le \rho_{l+1}$$

At the next position t_{i+s}, the following two conditions are checked to determine whether the interval [t_i, t_{i+s}] includes isosurfaces :

---

[2] A minmax map is an octree that has the minimum and the maximum value of the included cells.

Condition (a): $D(t_{i+s}) \geq \rho_{l+1}$

Condition (b): $D(t_{i+s}) < \rho_l$

When condition (a) is satisfied, the interval includes the ρ_{l+1} isosurface. The rendering algorithm thus calculates a shading value on the ρ_{l+1} isosurface and increases the level l by 1. When condition (b) is satisifed, the interval includes the ρ_l isosurface, so the rendering algorithm calculates a shading value on the isosurface ρ_l and decreases the level l by 1. This process is repeated until the sample position exits the volume or the accumulated opacity exceeds an opacity threshold.

An example is shown in Figure 6 for two isosurfaces, denoted by the density values ρ_1 and ρ_2. A sample ray is shown, and the initial level of the ray is zero. When the sampled value becomes greater than ρ_1 (here, at the point t_{i+s}), the algorithm finds the exact isosurface for ρ_1 (point **a**), increases the level of the ray by one and continues to find the next isosurface. At the point t_{i+s}, the sampled value is larger than ρ_2. The algorithm finds the exact isosurface for ρ_2 (point **b**), sets the level of the ray to two, and continues. The opposite case occurs at the point t_{i+2s}, where the sampled value becomes smaller than ρ_2. In this case, the algorithm finds the isosurface for ρ_1 (point **c**), and decreases the level to one.

6. Experimental Results

Our algorithm was implemented on a Silicon Graphics Onyx 10000 (a 196 Mhz R10000 processor, Infinite Reality Graphics Board, 512 Mbytes main memory) and on a Pentium II personal computer (a 450Mhz processor, a Matrox Graphics Millenium G200 graphics board, 320 Mbytes main memory).

The algorithm was applied to the Visible Man dataset to show its ability to handle a large dataset. The Visible Man dataset is available through the National Library of Medicine [7]. We used the first 512 slices

from the CT dataset (512x512, 8 bits[3]). The size of total dataset is 128 Mbytes. The sample images rendered using our algorithm are shown in Figure 7. Figure 7(a) shows the rendered image for two surfaces, skin and bone. Figure 7 (b) and (c) show rendered images for one isosurface, skin and bone, respectively.

Table 1 shows the performance in generating the images shown in Figure 7. For comparison purposes, we also implemented the PARC algorithm for multiple isosurfaces. We measured the rendering time for four cases : 1) standard isosurface ray casting with no optimization, 2) PARC algorithm, 3) image-space bounding surface only and 4) all optimization techniques. As described in Section 3, the rendering times of case 3 and case 4 are divided into 3 components, a) polygon rendering, b) ray casting and c) bounding surface generation.

In the PARC algorithm, the polygon rendering time depends on the macrocell size. We tested the PARC algorithm using "2x2x2" to "16x16x16" macrocells. The rendering times of the PARC algorithm reported in Table 1 are the best results found. In our algorithm, the rendering time is related to the rotation angle between successive renderings. The rendering times of case 3 and case 4 in Table 1 were acquired when the images were rotated 5 degrees around x and y axes from the previous images. If an image is rotated 20 degrees, it requires about 20 percent more rendering time.

Table 1 shows that our algorithm is about 1.8-3.8 times faster than PARC algorithm. For example, in rendering Figure 7(c) on the PC, case 1 took 21.24 seconds, case 2 took 1.63 seconds, case 3 took 0.59 seconds and case 4 took 0.51 seconds. Using all optimizations, our algorithm(case 4) is 3.2 times faster than the PARC algorithm(case 2) in this example.

To show the efficiency of our algorithm, we measured surface extraction times and polygon rendering times using the marching cubes algorithm in the Visualization Toolkit [9] and the same dataset. To extract the skin and bone isosurfaces from the dataset, it took 206 seconds and 220 seconds, respectively, in the SGI Onyx. The surface rendering time for extracted isosurfaces was more than 2 minutes in each case. Compared with our rendering time, the result is almost 100 times longer.

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[3] Originally, the pixel size of the Visible Man CT dataset is 12 bits. To fit the whole dataset into the main memory, each pixel was converted

Table 1 also shows that the other optimization techniques, LF-minmax map and memory bricking, become more effective when an image for multiple isosurfaces is generated because traversal operations can be simplified by the techniques. For example, in rendering Figure 7(a) on the PC, case 4 (1.53 seconds) is 1.91 times faster than case 3 (2.92 seconds). However, in rendering Figure 7(b) on the PC, case 4 (0.66 seconds) is only 1.15 times faster than case 3 (0.76 seconds).

Figure 8 and Figure 9 show example images rendered by our algorithm. Figure 8 shows some images with a cutting plane using two datasets, CT head (256x256x225, 8 bits) and MR brain (128x128x84, 8 bits). These images show the ability of our algorithm to render multiple isosurfaces of good quality on a PC platform. Figure 9 shows the images as the isosurface of interest changes with the CT head dataset.

7. Conclusion and Future Work

This paper presented an interactive ray casting algorithm for a large dataset. To accelerate isosurface ray casting, we proposed an image-space bounding surface. An image-space bounding surface is used to prune out unnecessary regions of volume. Regardless of the size of the dataset, an image-space bounding surface can be interactively rendered by inexpensive polygon rendering hardware. The algorithm also employs LF-minmax map and memory bricking for fast searching of isosurfaces. The experimental results show that the new algorithm generates a high-quality image, 1.8-3.8 times faster than PARC algorithm.

In our experience, the rendering performance of the optimization techniques is affected by the characteristics of volume data. Therefore, in future work, how the structural characteristics of volume data affect the performance of optimization techniques should be studied.

As hardware is being developed rapidly, new rendering techniques that take advantage of hardware are required. This paper discussed how to use standard graphics hardware in isosurface ray casting. In the future, other hardware, such as parallel processors, might be used with this algorithm to improve the rendering time.

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to 8 bits. The quality of the images might be affected by this conversion.

Acknowledgements

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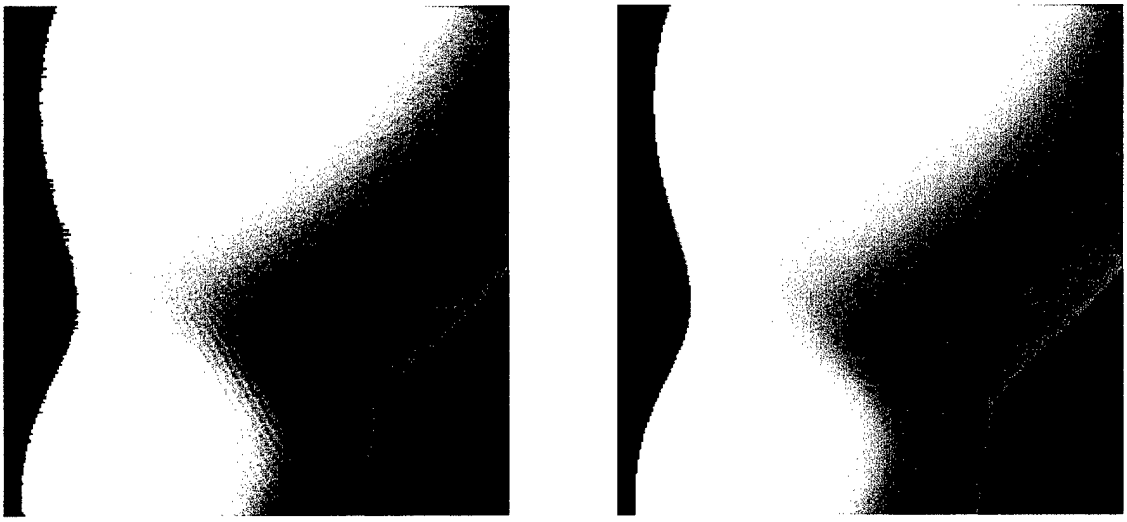
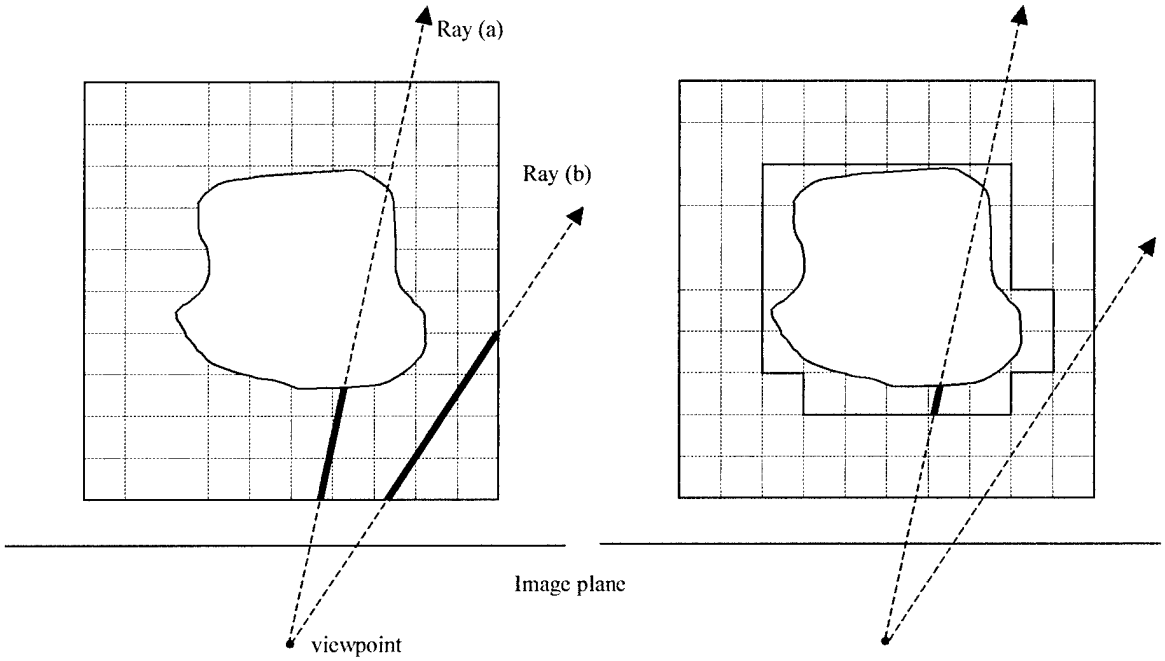


(a) Analytic method (b) Interpolation method

Figure 1. Images rendered by isosurface ray casting algorithm. An analytic method is used to generate image (a), and an interpolation method is used to generate image (b).



(a) brute-force **(b) bounding surface**

Figure 2. A 2D example of isosurface ray casting. When a bounding surface is applied to the ray casting, unnecessary volume traversal can be avoided.

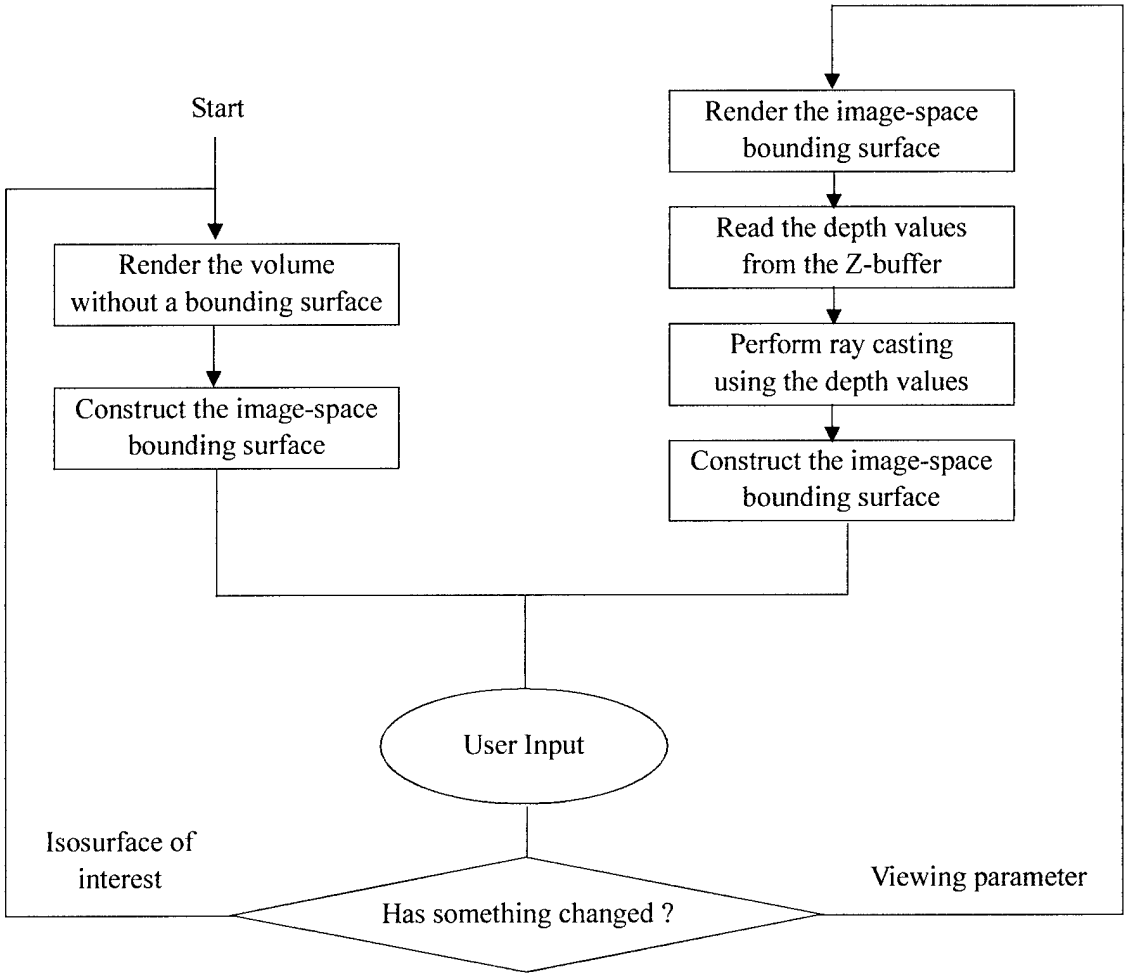


Figure 3. Flowchart of the image-space bounding surface algorithm.

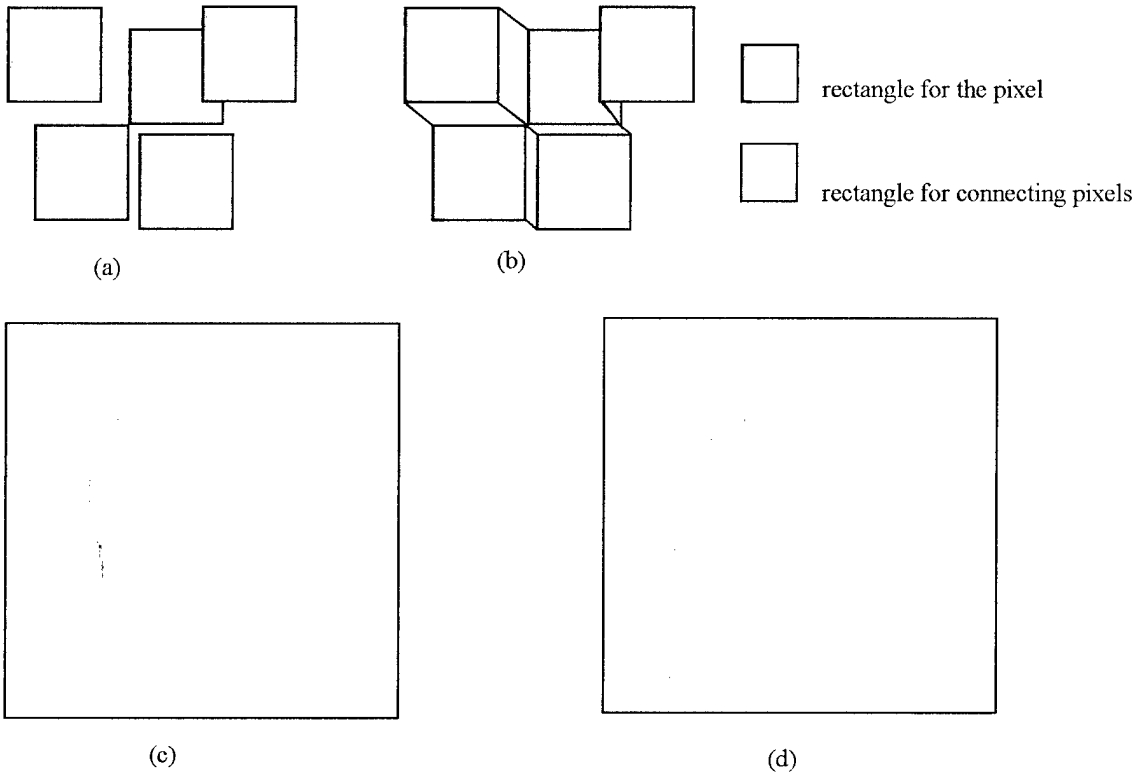


Figure 4. An image-space bounding surface is used to anticipate the pixels to be processed in the next image.

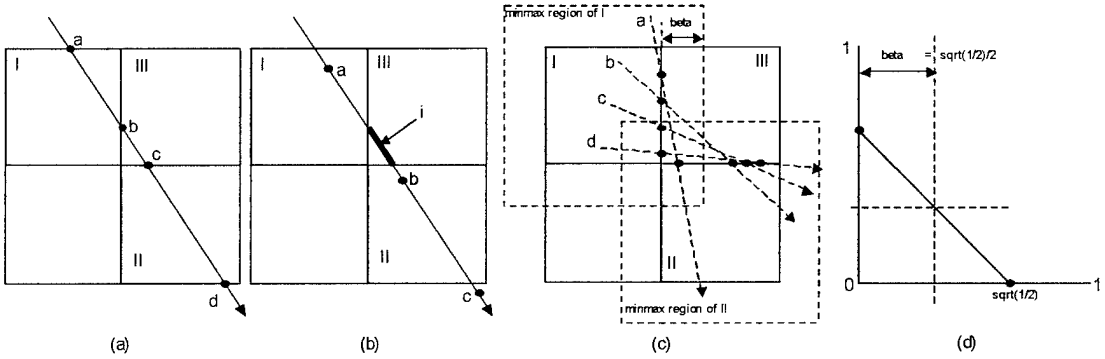


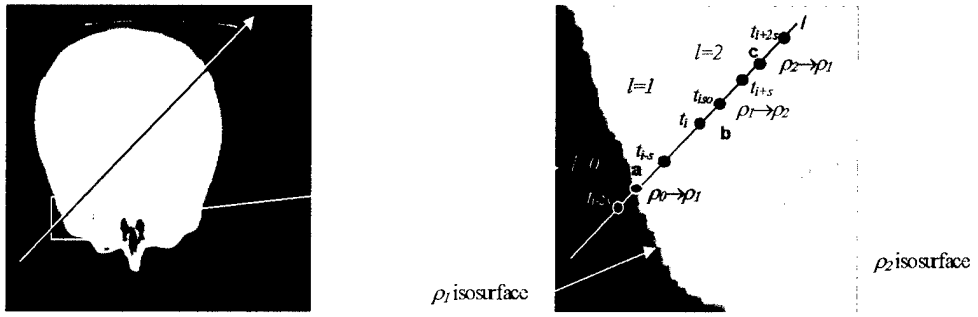
Figure 5. The construction process of LF-minmax map.

(a) Node a, b, c, d are checked when using an octree, which makes the advance operation complex

(b) Nodes are checked in regular step when using LF-minmax map

(c) The range of minimum and maximum value of each node in the LF-minmax map

(d) The appropriate β value when the size of node is 1x1x1

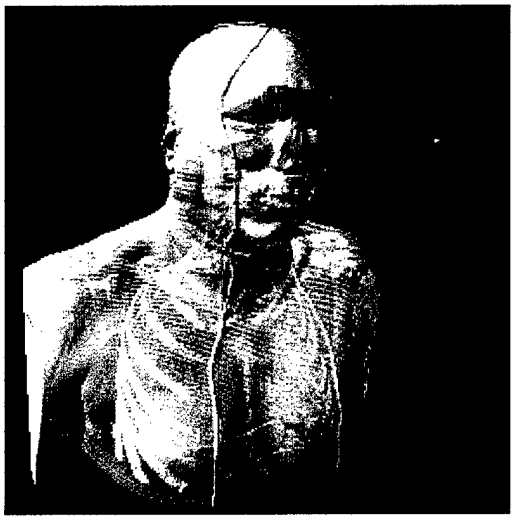


(a) **(b)**

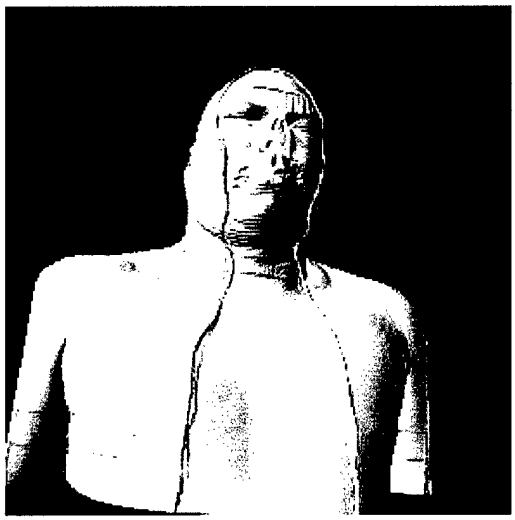
Figure 6. The multi-level isosurface ray casting algorithm

(a) A 2D slice image

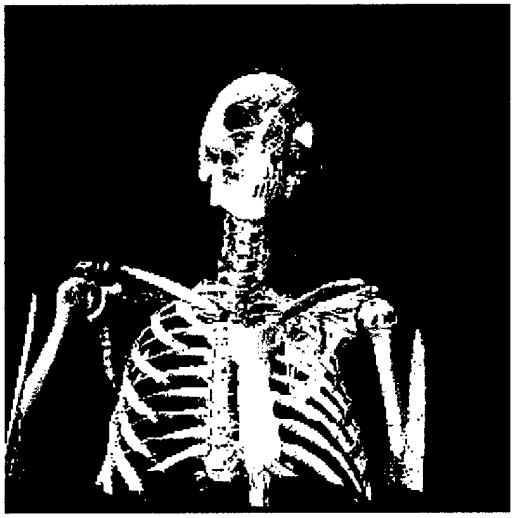
(b) A magnified view of the rectangle in (a). The image has two isosurfaces, ρ_1 and ρ_2. l is the level of the ray.



(a) two isosurfaces(skin+bone)



(b) one isosurface(skin)



(c) one isosurface(bone)

Figure 7. Rendered Images from Visible Man Dataset (512x512x512, 8 bits per pixel). The resolution of the images are 256x256.

(a) Bighead – 2 isosurfaces

(b) Brain – 1 isosurface

Figure 8. The sample rendered images. Bighead CT (256x256x225) and Brain MR (128x128x84) datasets are used.

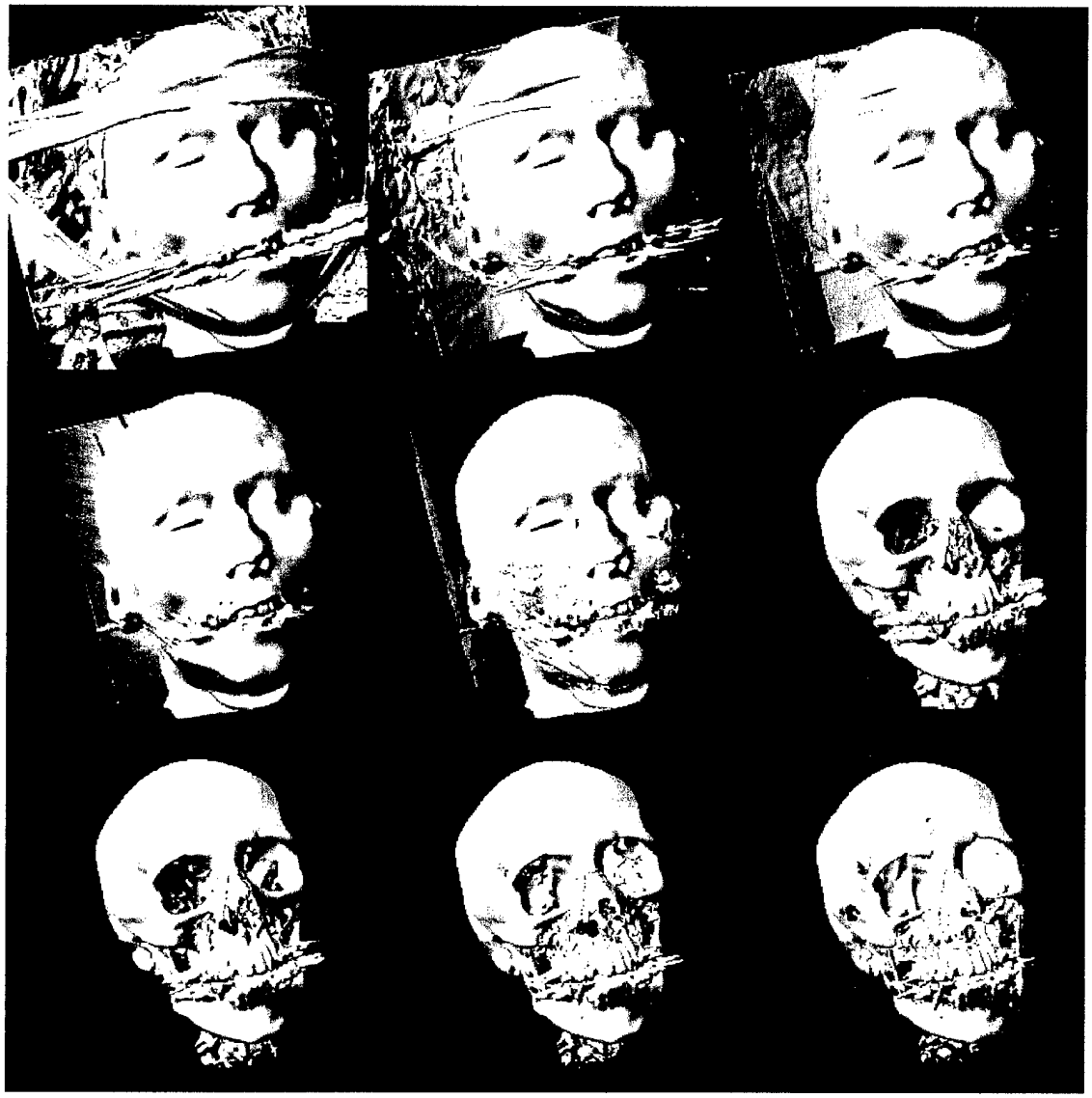


Figure 9. The images from the different isosurfaces (CT Head, 256x256x225, 8 bits).

Table 1. Rendering Time for Figure 7.

The rendering time of our algorithm is 1.8-3.8 times faster than PARC algorithm

(unit : seconds)

		Figure 7 (a)		Figure 7 (b)		Figure 7 (c)	
		SGI	PC	SGI	PC	SGI	PC
Standard isosurface ray casting with no optimization		26.6	21.19	23.9	18.40	27.3	21.24
PARC(Polygon Assisted Ray Casting)		5.25	4.15	1.65	1.20	2.2	1.63
Image-space Bounding Surface Only	Total Rendering Time	2.82	2.92	0.93	0.76	0.90	0.59
	Polygon Rendering	0.04	0.13	0.04	0.15	0.02	0.10
	Ray Casting	2.58	2.67	0.69	0.49	0.74	0.41
	Bounding Surface Generation	0.20	0.12	0.20	0.12	0.14	0.08
All Optimization Techniques	**Total Rendering Time**	**1.60**	**1.53**	**0.74**	**0.66**	**0.58**	**0.51**
	Polygon Rendering	0.05	0.15	0.04	0.15	0.02	0.10
	Ray Casting	1.28	1.26	0.50	0.39	0.42	0.33
	Bounding Surface Generation	0.20	0.12	0.20	0.12	0.14	0.08
Speed-up Factor	No Optimization/ All Optimization Techniques	**16.6**	**13.8**	**32.3**	**27.9**	**47.1**	**41.6**
	PARC/ All Optimization Techniques	**3.3**	**2.7**	**2.2**	**1.8**	**3.8**	**3.2**

10.2.3 Cleary 2001a: Technology improvements for ...

Reprint begins on the next page and is 18 pages.

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Technology Improvements for Image-guided and Minimally Invasive Spine Procedures

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I. ABSTRACT

This paper reports on technology developments aimed at improving the state of the art for image-guided, minimally invasive spine procedures. Back pain is a major health problem with serious economic consequences. Minimally invasive procedures to treat back pain are rapidly growing in popularity due to improvements in technique and the substantially reduced trauma to the patient versus open spinal surgery. Image guidance is an enabling technology for minimally invasive procedures, but technical problems remain that may limit the wider applicability of these techniques.

The paper begins with a discussion of low back pain and the potential shortcomings of open back surgery. The advantages of minimally invasive procedures are enumerated, followed by a list of technical problems that must be overcome to enable the more widespread dissemination of these techniques. The technical problems include improved intraoperative imaging, fusion of images from multiple modalities, the visualization of oblique paths, percutaneous spine tracking, mechanical instrument guidance, and software architectures for technology integration.

Technical developments to address some of these problems are discussed next. The discussion includes intraoperative CT imaging, MR/CT image registration, 3D visualization, optical localization, and robotics for percutaneous instrument placement. Finally, the paper concludes by presenting several representative clinical applications: biopsy, vertebroplasty, nerve and facet blocks, and shunt placement.

The program presented here is a first step to developing the physician-assist systems of the future, which will incorporate visualization, tracking, and robotics to enable the precision placement and manipulation of instruments with minimal trauma to the patient.

II. INTRODUCTION

Back pain is the major source of chronic disability in the United States[1]. Each year, the treatment and loss of work associated with back pain have an economic impact in excess of 50 billion dollars in the US alone[2, 3]. Although open techniques of surgical repair and augmentation of the spine are widely practiced with good success, the comorbidities of open back surgery are serious and well documented. First, open back surgery requires extensive soft tissue dissection. Muscle retraction during surgery has been shown to do short term damage and to affect long term, degenerative changes[4-6], which increase the patient's susceptibility to re-injury[7]. Most of the recovery involved in open spinal procedures is due to the soft tissue dissection and muscle trauma involved[8]. This trauma incurred in open spinal surgery necessitates long recovery time and extended loss of work[2, 9]. Recovery from open spinal surgery exposes the patient to prolonged opiate analgesia. Pain management researchers agree

that such analgesia poses a non-trivial risk of initiating, or exacerbating, addiction in the recovering patient[10, 11].

Minimally invasive approaches to spine surgery decrease tissue damage associated with open techniques. This has been shown to shorten hospital stay, speed recovery, lessen the long-term muscle wasting effects of open surgery, and spare the patient exposure to possibly addicting opiate medication. Together, these benefits promise to decrease the cost of treating spine disease while retaining the effectiveness of open approaches.

Minimally invasive spine procedures are rapidly growing in popularity due to improved techniques and decreased trauma to the patient[12]. Percutaneous spine procedures are a type of minimally invasive technique in which thin, tubular instruments are placed and then manipulated through the skin to treat a variety of spinal conditions. Percutaneous techniques for biopsy, vertebroplasty, nerve and facet blocks, laser and radiofrequency ablations, among others, are widely practiced[8, 13].

This paper reports on the development of a program in image-guided percutaneous spine procedures at the Imaging Sciences and Information Systems (ISIS) Center, which is a medical imaging group in the Department of Radiology at Georgetown University Medical Center[14]. This program is a multidisciplinary effort between engineers and physicians aimed at creating new techniques for image-guided spine procedures.

Several technical problems have been identified that must be overcome to advance the state of the art in the field of minimally invasive surgery. These problems will be described in the next section, followed by a description of technical developments in progress to address these difficulties. The clinical investigations undertaken to evaluate these advances are then briefly described.

III. TECHNICAL PROBLEMS

While minimally invasive and image-guided techniques have already been developed in many institutions, some technological problems remain unresolved[15, 16]. Some of the principal obstacles to enabling image-guided, minimally invasive techniques include:

1. Optimal intraoperative imaging is not widely available: Percutaneous approaches to the spine depend on adequate imaging of underlying anatomy. Conventionally available fluoroscopic visualization does not provide a 3D image for precise targeting and path planning. Intraoperative CT allows adequate visualization of spinal bone and 3D image capability.
2. CT and MRI spine images not concurrently available: CT and MRI spine images provide different information about bone and soft tissue structures, both of which are useful in planning and execution of diagnosis and treatment. Because CT and MRI images cannot be obtained concurrent with surgery at a reasonable cost, these images need to be registered into a single image that can be made available in the operating room.
3. Oblique paths cannot be visualized: three-dimensional (3D) visualization and graphical overlay of instruments in 3D will allow oblique paths to a target that crosses several adjacent axial CT slices.
4. Tracking is limited: Percutaneous spine tracking is not available. Tracking of the spine and surgical instruments with graphical overlay on medical images will allow path planning and path recording. Percutaneous spine tracking would allow precise intraoperative image guidance by correcting for intraprocedural spine movement.
5. Instrument placement slow and inaccurate: mechanical instrument guidance will assure accurate placement of instruments from the skin entry point to the target and increase the speed of minimally invasive surgery.

6. A software architecture for the integration of imaging, localization, and robotic instrumentation is does not exist. Current surgical navigation systems employ proprietary software interfaces between fixed instrument types. A more flexible, component-based software framework for integrating technologies is needed.

While some of these problems have been solved in specific domains, there is still a great deal of work to be done. In our program, we will directly address these issues and plan to leverage the efforts of other researchers wherever possible to achieve a comprehensive approach to these problems.

IV. TECHNICAL DEVELOPMENTS

The long-term goal of our research program is to develop an integrated system to enable the next generation of percutaneous spine procedures. The equipment and techniques developed are intended to be transferable both to other classes of minimally invasive spine intervention (key-hole access and endoscopic procedures) and non-spinal percutaneous applications as well. As one of our first steps in this effort, we are assembling a robotic biopsy testbed to serve as a platform for development and integration. The technical developments that comprise the testbed include: 1. a mobile CT scanner; 2. MRI/CT image registration; 3. 3D image visualization; 4. position tracking; 5. a small "needle driver" robot; and 6. software integration of the system components. These technical developments are intended to address the unresolved technical problems discussed in the preceding section. In addition to providing a framework for development, the testbed will be used to compare robotically assisted biopsy to the current manual technique. It will also allow us to investigate software architectures for integrating multiple medical devices. A system diagram is shown in Figure 1. This work is part of our collaboration with the Urology Robotics Laboratory of the Johns Hopkins Medical Institutions, under the direction of Dan Stoianovici, Ph.D. and the Computer Integrated Surgical Systems and Technology (CISST) Engineering Research Center at Johns Hopkins University, under the direction of Russell Taylor, Ph.D.. In the following sections, we will discuss each of the components of the testbed in some detail, and suggest how they contribute to enabling the next generation of percutaneous spine procedures.

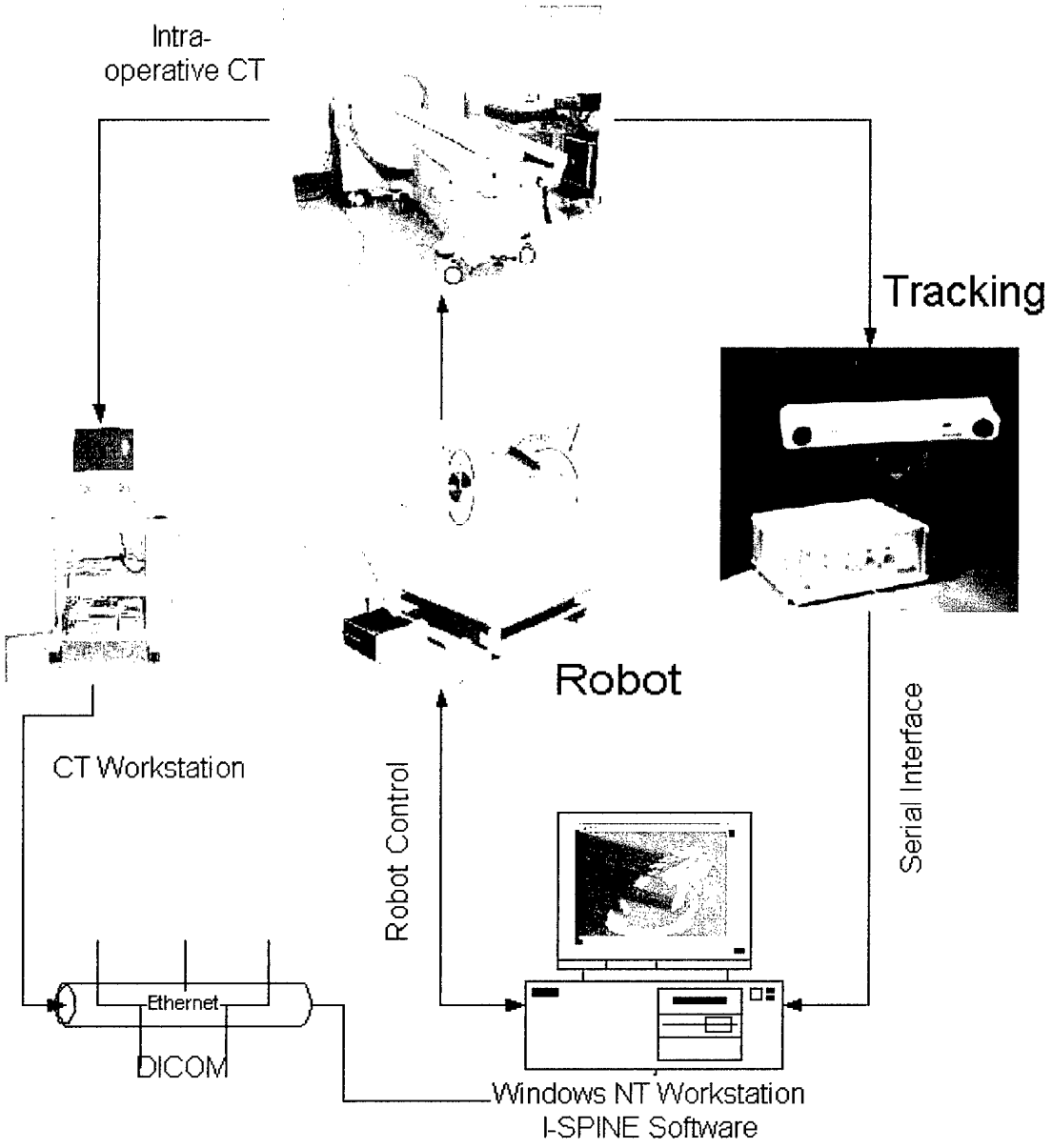


Figure 1: Robotically Assisted Biopsy System Concept

A. Intraoperative Mobile CT

Accurate intraoperative visualization of spinal anatomy is a crucial element in enabling the minimally invasive, percutaneous spine surgery currently in development[16]. Precision in spinal procedures is critical because of the proximity to nerve roots and spinal cord. Any minimally invasive approach to the spine depends on high quality imaging to negotiate this complex anatomy when surgical opening is small. CT images of the spine provide more information about vertebral anatomy than images obtained with currently available intraoperative modalities such as fluoroscopy or ultrasound[17]. Intraoperative CT promises to provide the interventionalist with a means to evaluate spinal anatomy, correct surgical path, and assess instrument placement. The accuracy of tip definition with new-generation CT machines is within

1 mm^3 [18, 19], which is considered sufficiently accurate for surgical planning and intraoperative targeting[20].

As an initial step in our research program, we have integrated a mobile CT scanner (Philips Tomoscan) to provide intraoperative images [21]. The first report of on-demand CT in an operating room setting was Butler, et al. [22], and intraoperative CT has since become available in several medical centers throughout the US[23, 24]. At Georgetown, the mobile CT scanner has been used in interventional radiology, the operating room, radiation medicine, the neurosurgery intensive care unit[25], and the pediatrics ICU[26]. The major procedures impacted by the availability of intraoperative CT are in interventional radiology and in neurosurgery. Since May of 1998, the mobile CT has been used in over 100 procedures at our institution. The CT scanner is an FDA approved device. Since both the gantry and the table can move during scanning, the gantry can be used with the CT table (as done in the operating room) or with another table such as a fluoroscopy table (as done in the interventional suite).

In neurosurgery, we have used the mobile CT to provide support for complex open back procedures, particularly the treatment of craniocervical lesions and spinal cord tumors. In such cases, adequate visualization of the extent of tumor and the complex anatomy has proven instrumental in successfully removing adequate tumor tissue without incident. Our experience with neurosurgical spine patients shows that the use of intraoperative CT scanning changed the course of the surgery in 6 out of 17 cases[25]. CT proved beneficial in facilitating adequate ventral clival and craniocervical decompressions, assisting in more complete tumor resections, and verifying correct graft and instrument placement before surgical closing. We have also used the mobile CT extensively in neurointerventional radiology for adequate intraoperative guidance and postoperative assessment for vertebroplasty, biopsy, and nerve and facet blocks. Our experience with these procedures is detailed in Section 5, Clinical Applications.

B. MRI/CT Image Registration

Implementation of percutaneous spine intervention requires adequate knowledge of tissues in and near the target site of surgery. Currently, no single imaging technology is sufficient for imaging both bone and soft tissue adequately[15]. CT is best for visualizing bone and certain soft tissue structures. It also provides superior instrument tip visualization, which is critical when navigating in high risk areas, like the spine[19]. MRI is superior for imaging soft tissue and particularly in differentiating protruded discs from surrounding anatomy[17, 27]. It would be, for most sites, cost prohibitive to utilize MRI in the operating room except for the most critical procedures. Intraoperative CT is far less expensive and increases the practicality of intraoperative visualization.

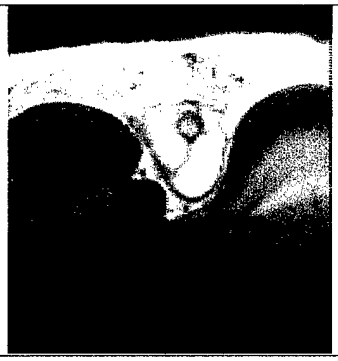
Rather than relying on intraoperative CT and MRI imaging for image guidance, one goal of our research effort is to utilize registered, preoperative CT/MR images. Image registration will allow us to fuse CT and MR imaging data to permit visualization of soft and bony structures in a composite image. This offers the physician optimal visual information about the target anatomy. This fused image data can then be used to generate 3D renderings of the anatomy to serve as 3D map for intraoperative surgical navigation[28, 29]. Usage of preoperative images for surgical navigation requires the additional step of registering patient and instrument locations to the image. Intraoperative CT scans would then be used to verify instrument placement and surgical outcome if deemed appropriate.

Image registration for spine images is not currently a solved problem[30, 31]. There are basic registration programs available, but these do not correct for the slight shifting that can occur between two different vertebrae upon patient motion or in course of surgical manipulation. In collaboration with Lou Arata, PhD, of Picker International (now Marconi), we have presented preliminary results on registration of CT and MRI images and an example of a registered image is provided as Figure 2[32]. In the initial stages of our program, we are relying on preoperative CT

images to provide image guidance, with the intention of introducing MRI co-registration when our technical advances permit.

Preoperative MRI

Intraoperative CT (note the surgical incision)



Registered MR and CT

Figure 2: Preoperative MRI and Intraoperative CT Registration (courtesy of Lou Arata, PhD, Picker International)

C. 3D Visualization

3D reconstruction of MRI and CT images of the surgical field promises to provide optimal information for surgical guidance and instrument manipulation in minimally invasive surgery. Using properly displayed 3D images the physician will have adequate information about the relationship of the target abnormality to surrounding structures despite minimal surgical opening. This information will permit the physician to determine the best approach to the target tissue and make the most rapid and accurate decision about appropriate treatment. 3D visualization is expected to be particularly helpful in planning and implementing oblique directions for the placement of instruments. As the importance of minimally invasive surgery increases, it is inevitable that standards for obtaining, displaying, and analyzing 3D images will develop, although currently no such standards exist[15].

3D visualization in spinal surgery will permit the easier placement of instruments that cross from one imaging slice to adjacent slices, whether these instruments are needles being placed in vertebra or screws installed across facet joints for fusion. In spine decompression surgery, it will allow improved understanding of the interconnection and displacement of bony fragments and should allow improved methods for their removal or displacement. Initially, we plan to develop techniques for the intraoperative 3D display of computed tomography (CT). Later, we plan to develop methods for the 3D display of fused images incorporating pre-operative MRI and intraoperatively obtained CT images.

As an initial study to demonstrate the utility of 3D reconstruction, 3D visualization software was developed to examine the spread of bone cement after vertebroplasty procedures[33]. This visualization software is part of a larger software package called the ISIS Center Spine Procedures Imaging and Navigation Engine (I-SPINE)[34]. The images for study were acquired by the mobile CT scanner. Offline, these images were then transferred to a Windows NT personal computer using the digital image communications in medicine (DICOM) standard. The I-SPINE software was then used to segment the bone cement and vertebral body based on histogram windowing (Figure 3). The resulting images are rendered in 3D for viewing by the interventional radiologist (Figure 4). At the moment, only preliminary work has been done, but the interventional radiologist has stated that the images are useful for visualizing the spread of

bone cement. Related research has also been done on developing improved visualization algorithms[35].

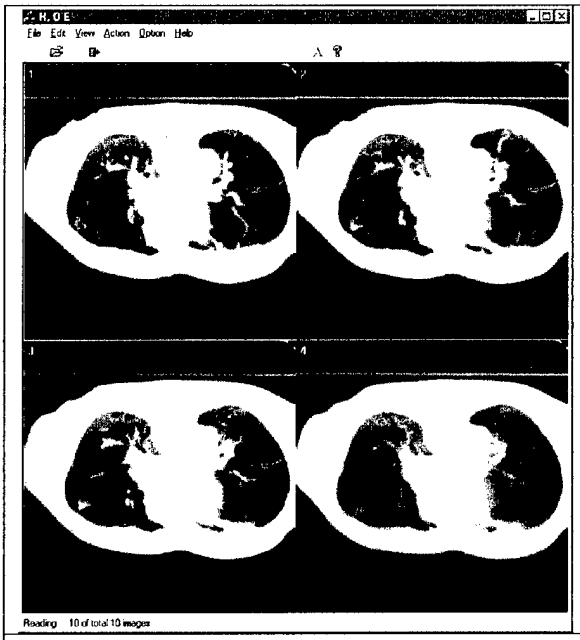


Figure 3: Axial CT images

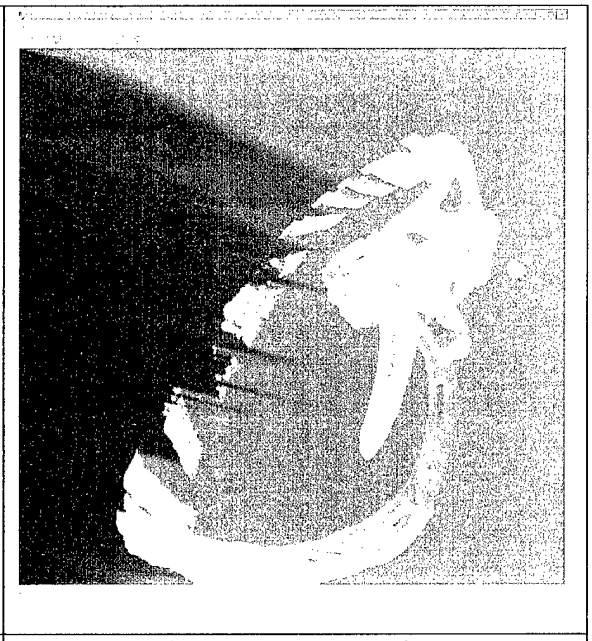


Figure 4: 3D Rendering

D. Optical localization and registration

In order to provide the physician with optimal information about the surgical field, and to assure maximum accuracy in a minimally invasive procedure, it is essential to pinpoint the locations of instruments, anatomical structures, and operating room landmarks in three-dimensional space and in relationship to one another. This process is referred to as localization or tracking. Tracking will permit matching, or "registration" of the surgical space to image space, as represented by preoperative MRI and CT images. Registration of image and surgical space allows the physician to use the registered image as a reliable 3D "map" for operative planning and intraoperative guidance. This use of patient and instrument registration, while relatively new to spinal applications, is widely used in neurosurgery. These "frameless stereotactic" systems for intercranial localization and targeting are widely commercially available and have achieved high levels of accuracy[36].

Current techniques of percutaneous spine intervention, applied without instrument and spine tracking registered to image guidance, risk compromised accuracy for several reasons. First, individual and adjacent vertebrae have been shown to move substantially in relationship to one another during surgery due to breathing and surgical manipulation. Movement of up to 1.3 mm, peak to peak, has been reported from breathing alone, at the lumbar level[37]. Vertebral tracking and image guidance is considered standard of care in pedicle screw placement, for example, because imaging alone has been shown to be insufficiently accurate[38, 39]. Without vertebral tracking and intraoperative image guidance, the inteventionalist is required to rely on successive steps of needle placement, image verification, needle advancement, and re-imaging, and so on until the target is obtained. This slow approach to the target increases the likelihood of intraprocedural patient movement and instrument shifting due to gravity. Percutaneous spine tracking promises to eliminate these sources of inaccuracy and provide maximally precise targeting.

Several classes of tracking technology exist, each with attendant strengths and drawbacks. Optical, magnetic, mechanical, and ultrasonic position digitizers are available[40].

At Georgetown, we are investigating both optical and magnetic tracking systems for tracking of the spine.

The optical tracking system we use (Hybrid Polaris, Northern Digital, Waterloo, Canada) is shown in Figure 5 and determines the orientation and position of tracked objects relative to a camera system. Objects are tracked by rigidly attaching retro-reflective spheres or active infrared LED's (IREDs). The spheres or IREDs can be detected by the camera system and used to determine the location and orientation of the object. The current version of the Polaris can track up to three active and three passive tools simultaneously and is controlled via the serial port of the host computer.

By attaching reflective spheres directly to the CT table, we are able to track the CT table and gantry. Similarly, tracking spheres located on the robot and end effector will enable us to directly monitor the robot position. This is especially important as a safety feature to verify the robot's own encoders. Finally, dynamic reference base tracking (DRB) as shown in Figure 6 implanted percutaneously into vertebral bone will allow tracking of spine movement. Intraoperative tracking of spinal anatomy, the operative environment, and the robot end effector will allow for updated image registration and real-time image-guidance.

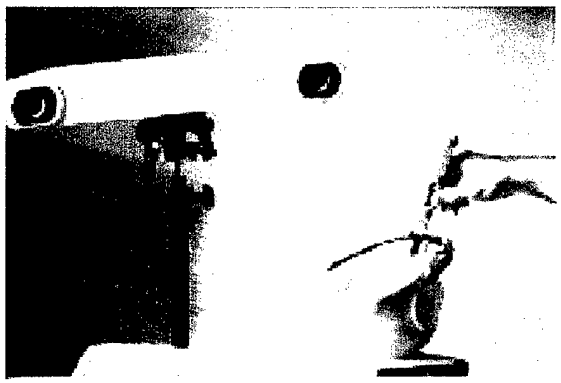


Figure 5: Hybrid Polaris (courtesy of Northern Digital, Inc.)

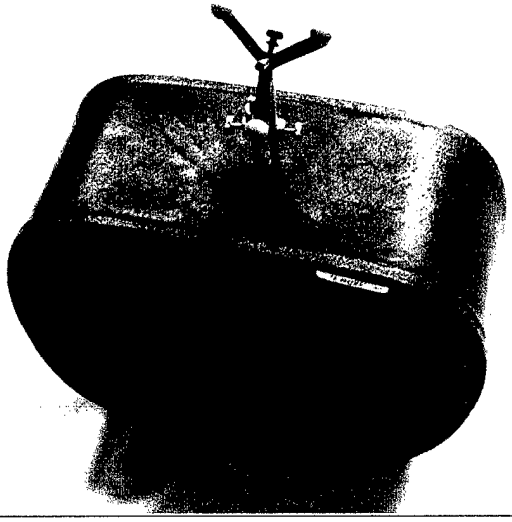


Figure 6: Interventional Phantom with Dynamic Reference Base Attached

Optical tracking systems in general, and the Hybrid Polaris in particular, are characterized by a high degree of accuracy[41]. The major drawback of optical systems is the requirement that a "line of sight" between the trackers and the camera remain at all times. This line of sight requirement can be cumbersome and difficult to maintain in the delicate surgical environment, or when intraoperative imaging is required, and may reduce the acceptance of image-guided spine surgery among physicians[42, 43]. In an attempt to compensate for these difficulties, we are currently evaluating a soon-to-be commercially available magnetic position digitizer (the Aurora from Northern Digital). This tracker represents a new generation of DC magnetic trackers with increased accuracy and stability even in ferromagnetic environments[44]. Ongoing research work at our lab is dedicated to comparing the accuracy and resiliency of the magnetic system in comparison to the well-characterized optical system. The tracker's sensors are small (.9 mm diameter) and potentially can be embedded into spinal bone or paraspinal tissue. The main advantage of magnetic tracking is that no line of sight need be maintained.

E. Mechanical Guidance

Robotics were introduced into the surgical arena in the 1980's with the primary purpose of improving precision. Intracranial neurosurgical procedures were the major focus of the first robotic systems, in part because a high degree of precision is required for localization and manipulation within the brain, and because cranial anatomy provides relatively fixed landmarks. Medical robotics has since expanded to other clinical applications. Many prototype robotic systems have been developed, but presently only a few systems are available commercially[45, 46].

To the best of the author's knowledge, there are no other research groups specializing in robotics for spine procedures. At Georgetown University Medical Center, we are developing a robot guidance system for percutaneous spine procedures in collaboration with the Urology Robotics Laboratory (URobotics Lab) of the Johns Hopkins Medical Institutions and the Computer Integrated Surgical Systems and Robotics Center of Johns Hopkins University. The system is aimed at increasing the precision and efficiency of instrument placement and manipulation during percutaneous spine procedures. We believe that this will lead to better patient outcomes, but this remains to be seen.

The robotic device will be based on the RCM-PAKY (Remote Center of Motion /Percutaneous Access of the Kidney) Robot, which has been developed at Johns Hopkins and applied to percutaneous access of the renal collecting system[47-49]. The robot, schematically represented in Figure 7, consists of a passive positioning and supporting arm (the GREY arm), an active remote center of motion orientation mechanism (RCM) and a radiolucent needle driver (PAKY). The device will be mounted over the CT table using a bridge fixture as shown in Figure 8.

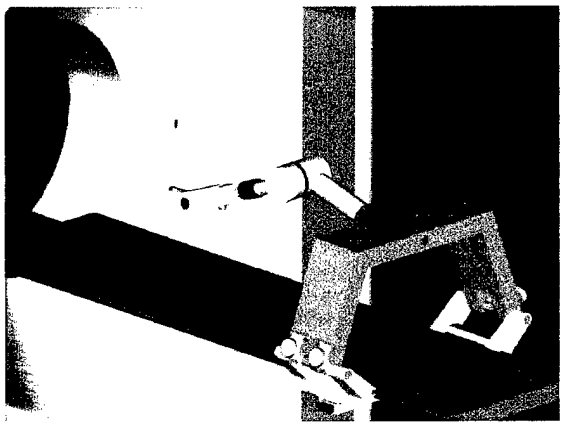


Figure 7: CAD Rendering of Robot Mount and Arm on CT Table
(Courtesy of Dan Stoianovici, PhD, Johns Hopkins Urology Robotics)

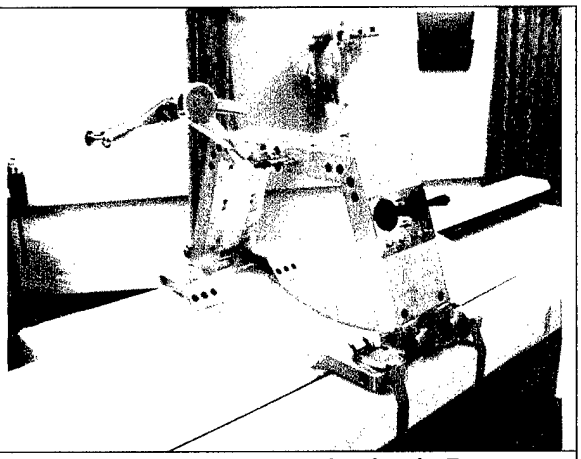


Figure 8: Hardware Fabrication in Progress and Mounted on CT Table
(Courtesy of Dan Stoianovici, PhD, Johns Hopkins Urology Robotics)

The overall system comprises 11 degrees of freedom (DOF). The first eight DOF are used for initial positioning of the robot in close proximity of the skin insertion site and firmly locked during the operation. The remaining three degrees of freedom, implemented by the RCM robot and PAKY needle driver, are sufficient for orienting and inserting the needle at the desired target through the preset skin insertion point. The main advantage of this minimal kinematic architecture is the inherent safety given by the restricted mobility of the mechanical components. Moreover, separating the kinematics of orientation from needle insertion yields decoupled needle motion capabilities, thus further increasing safety.

The needle driver is constructed of acrylic plastic which is radiolucent and easy to manufacture as a sterile disposable part. Driver radiolucency is essential to image-guided procedures for providing unimpeded target visualization. Whereas the driver is sterilized, in clinical use the additional components of the system in close proximity to the operative site are covered with a sterile bag.

The robot accommodates joystick control for simple maneuvers and full computer control for the actual image-guided procedure. The electronic circuitry will be fully enclosed in the supporting bridge of the arm, so that the robot is self-contained and only requires a DC power supply.

The complete system is currently under development. The new design incorporates a major improvement over the first generations of the RCM robot, the "ball-worm transmission" recently developed at the Hopkins URobotics Lab[50]. This transmission fulfills the need for implementing simple and small no-backlash (no play between the input and output shafts) rotational transmission for miniature surgical robots. With this addition the RCM should exhibit superior motion tracking and positioning capabilities.

F. Software Integration

To analyze and manipulate the images used in this project, we have developed our own software package, called I-SPINE (ISIS's Spine Procedure Imaging Navigation Engine) as described in Section 3[34]. I-SPINE is a Windows NT application, which is based on the Analyze/AVM™ libraries. The software architecture follows the Microsoft Foundation Classes (MFC) single document, multiple view paradigm. This has allowed the developers to add new visualization modules to I-SPINE that aid physicians in procedures outside the spine. These specialized applications have included 3-D visualization of bone cement for vertebroplasty and uterine fibroid embolization.

The I-SPINE software currently includes the following capabilities:

- DICOM receiver to accept images from mobile CT, fluoroscopy, and DSA units at Georgetown and elsewhere
- 2-D viewing of DICOM images (single slices or multiple slices up to 8 by 8)
- Segmentation function based on volume histogram
- Multi-surface 3-D visualization for applications such as vertebroplasty
- Registration of DSA images by manual pixel shifting

Components of the operating room of the future will include some or all of the elements we have discussed: intra-operative imaging, 3D visualization, image registration, tracking, and mechanical guidance. The integration of these components through software presents some unique challenges. From a software engineering perspective, the integration task requires that a clear architecture be created that allows components to be introduced into (and removed from) the environment with minimal risk. These risk factors constrain the software architecture through complex requirements, such as quasi-real time performance, fault tolerance, security, and quality of service.

Standards for computer application interface in medicine have been developed for data transfer (ANSI) and image sharing (DICOM). No such standards exist, however, for integration of device control. We believe that the component based software engineering (CBSE) approach taken by the successful DICOM and ANSI standards can be used to create and architecture for medical device control, as well. CBSE is increasingly popular due to the explosive growth of the Internet and Object-oriented Analysis and Design (OOA&D) over the past decade. This has realized the vision of dynamic components that are described, located, and composed at run time over the Internet to produce applications with the specific behavior that the user requires. This is a significant departure from the monolithic, stand alone, "legacy" systems of the past. Component-based software systems promise increased reuse, flexibility, and maintainability compared to their legacy counterparts.

CBSE is currently applied primarily to application domains that manipulate purely information products. In order to extend this application to device control and integration, appropriate levels of real-time performance, fault tolerance, security, and quality of service will need to be achieved. It is our belief, however, that the benefits being reaped from the CBSE revolution can be applied to the problem of technology integration in surgical environments. We believe that the results will be a reduced cost of entry into the field to researchers and vendors alike, open platforms for robust integration, and systemic approaches of addressing system issues such as fault tolerance and quasi real-time performance.

For these reasons, we intend to apply pure CBSE practices to the integration of the technological developments outlined in this review. The mobile CT scanner, robot, tracking, I-SPINE visualization software, and image registration are conceived of as independent components to be integrated on a CBSE platform. Our goal is to provide an infrastructure that is scalable, efficient, fault-tolerant, and resilient to change. We hope to create an architecture that will allow the physician to choose and integrate precisely the components required for the procedure at hand. This will allow both the selection and integration of existing technologies in the operating room, and the incorporation of new technologies as they become available.

V. CLINICAL APPLICATIONS

Currently, percutaneous spine procedures are performed by freehand passage of instruments (such as a needle or trocar) from the skin surface to the spine. Based on imaging modalities such as X-ray fluoroscopy and/or computed tomography, the physician identifies the skin entry point and the target, thus defining the needle trajectory. The physician then aligns the instruments by hand and partially inserts it toward the target. The instrument is then released and the instrument position is checked with imaging to confirm proper targeting. As required, the physician may adjust the instrument in a free hand manner and then advance further. This process of "advance and check" is repeated until the instrument is adjacent to the targeted portion of the spine. The main problem with this approach is that the unaided human operator has limitations in accuracy when initially lining up the instrument and in staying on course. Additionally, when the physician lets go of the instrument, it may tilt out of alignment due to the effects of gravity, particularly when a large gauge trocar is used.

Strategies of image-guidance and computer assisted surgery, first developed for frameless stereotactic brain surgery[51, 52], have begun to impact this traditional mode of percutaneous spine work. However, acceptance of these strategies has been somewhat limited by several key remaining obstacles to their full implementation in the spine. In the following sections we will outline how the introduction of intraoperative CT imaging, 3D visualization, patient and instrument tracking, and robotic assistance can contribute to overcoming the obstacles remaining to the implementation of image-guided percutaneous spine intervention. In particular, we will focus on the application of these technologies to percutaneous pine biopsy, vertebroplasty for spine augmentation, and nerve and facet blocks. The extension of these advances to non-spinal percutaneous procedures will be suggested in a technique of anterior intrahepatic portal shunt placement (a variation of the transjugular TIPS procedure). It is expected that image-guided technologies will also impact minimally invasive approaches to spine stabilization, nerve root decompression, and tumor reduction, among others.

A. Biopsy

The goal of our research program is to develop an integrated system to enable the next generation of percutaneous spine procedures. As a first step in this effort, we are assembling a robotic biopsy testbed to serve as a platform for technology development and integration. The previously discussed technical developments that comprise the testbed include: 1. a mobile CT scanner; 2. MRI/CT image registration; 3. 3D image visualization; 4. position tracking; 5. a small "needle driver" robot; and 6. software integration of the system components. In addition to

providing a framework for development, the testbed will be used to compare robotically assisted biopsy to the current manual technique.

Freehand percutaneous spine biopsy is a frequently performed alternative to open biopsy. Accuracy of this procedure is reported at 85-92%[53, 54]. This level of success diminishes considerably in inexperienced operators and in biopsy of precariously placed lesions[54]. Biopsy of the lumbar and thoracic spine reports the highest levels of success and is the most routinely undertaken[55, 56]. Cervical spine biopsy is more difficult, with a higher rate of complication and lower reports of success due to the complexity of surrounding anatomy[57]. We predict that robotically assisted, image-guided biopsy will be able to target and sample lesions with 1.5 mm^3, exceeding the accuracy of the freehand technique[58]. We expect the rate of success to be higher for robotic biopsy of all spinal levels. Because freehand biopsy of the lumbar and thoracic spine is already quite successful, we assume that robotically assisted biopsy will prove most useful in enabling cervical spine biopsy and biopsy of anatomically precarious lesions.

We envision robotic biopsy would be carried out in the following manner:

Mobile CT scanner and operator's workstation. The mobile CT scanner provides a series of axial images of the patient. Each image is 512 by 512 pixels, and a typical data set consists of from 10 to 100 images. The operator's workstation provides a graphical user interface to operate the scanner. The only interface to the outside world is a DICOM interface, where the images can be sent over a network to another DICOM capable system. In this testbed, after the scans are acquired, they are sent to a Windows NT workstation running our I-SPINE software.

3D Visualization and path planning. After CT imaging of the relevant anatomy is obtained, 3D reconstruction and visualization is performed.

Patient and Instrument tracking and image registration. Using optical and magnetic tracking, the patient's vertebral bone, the CT table, and the biopsy needle are located in real space. This digital representation of the operative space is then registered to the CT image, providing a 3D "map" for path planning and targeting. Because the patient's movements are targeted in real-time, this map will be continuously updated to reflect the true position of anatomy in image space.

Path planning. The registered image and operative space, as represented by the workstation display, is used by the physician to plan the operative path. The target to be biopsied is identified. An appropriate path, avoiding sensitive intervening structures, is selected. This determines the appropriate skin entry point. Once the path has been planned, path information in the form of needle orientation and depth of drive are transmitted to the PACKY robot.

Robot. The robot will hold, automatically orient, and drive the biopsy needle in accordance with the physician's path plan. The robot is controlled by the NT workstation via a hardware and software interface.

Position verification: A CT image is obtained to verify needle location and determine distance from target.

The testbed is currently under construction and initial trials are planned using an interventional phantom.

B. Vertebroplasty

The introduction of mobile CT and 3D visualization into the interventional suite is impacting the performance of percutaneous vertebroplasty at Georgetown University Medical Center. Percutaneous vertebroplasty involves injecting polymethylmethacrylate (PMMA, or bone cement) into the vertebral body. It is currently performed to strengthen vertebral bodies that have been mechanically weakened, or to relieve pain from spinal fractures, both traumatic and pathologic[59, 60]. Such weakening can occur in metastatic invasion of the bone[61], or osteoporotic degeneration[62, 63]. As its long term efficacy and results become known and studied, vertebroplasty is becoming a first-line treatment for spinal disease[64].

Most patients experience significant pain relief within 24 to 48 hours following the procedure. Exact mechanisms for pain relief are unclear. Proposed theories include: filling of vertebral microfractures, reduced intra-body movement, and damage to nerve root fibers from the exothermic reaction during cement curing[65]. While still a "new" procedure compared to traditional, open vertebrectomy, percutaneous vertebroplasty has emerged as a powerful minimally invasive tool for treating bony spinal disease. Mobility is achieved much sooner post-operatively, and with better residual vertebral stability than with the open procedure[64].

The current technique of vertebroplasty relies on fluoroscopy for intraoperative imaging. At Georgetown, we are using the mobile CT as needed to ensure precise needle placement and after the procedure to check for extravisation. Extravisation of PMMA, and embolization into the paravertebral venous plexus, is a rarely reported but serious complication of vertebroplasty [66, 67].

C. Nerve and Facet Block

Percutaneous facet and nerve blocks are another treatment modality that relies on minimally invasive techniques. In these procedures, patients are positioned prone as described above for vertebroplasty. An 18-to-22 gauge spinal needle is localized to the desired facet or dorsal nerve root region with fluoroscopy, and an injection of a long acting anesthetic (such as bupivicaine) and or a steroid (such as celestone) is performed following confirmation of extra-vascular needle tip position. Pain relief may be obtained from minutes to weeks after injection/ablation; relief, or the lack it, may help physicians better evaluate the cause of a patient's back and limb symptoms.

Low back pain without sciatica is often caused by degeneration of the facet joints[27]. About 80% of facet syndromes are located in L4/L5 and L5/S1. Surgical neurolysis of facet joints was introduced in 1971 by Rees[68] and was followed a few years later by electrocoagulation. Facet joint block with local anesthetic or facet joint denervation with 50-96% ethanol are performed at Georgetown University Medical Canter under intraoperative CT guidance. Treatment produces good results in 65-75% of carefully selected patients. Mobile CT is useful in facet joint blocks to monitor the positioning of the needle and the spread of ethanol or anesthetic to prevent errors of injection into nerve roots or vessels. The application of the full image-guidance and robotic assistance paradigm detailed in the biopsy testbed could further increase the safety and precision of this procedure.

Nerve root infiltration for nerve block or neurolysis requires extreme accuracy to fulfill its diagnostic and treatment purposes. Injection of anesthetic in the wrong location can cause blockade of adjacent nerves, muscle, and periosteum, with subsequent pain relief causing misidentification of the true cause of pain, and possible later mistaken neurolysis. Worse, injection of local anesthetic into vertebral artery can cause convulsions immediately[69]. Negative aspiration is not enough to ensure safety in the absence of CT guidance[27]. One survey of freehand needle placement in nerve sheath infiltration showed inaccuracies of up to 3 mm3, with extensive diffusion of anesthetic[70]. A high degree of precision and small quantity of injected anesthesia (.5 cc or less) are desirable to optimize diagnostic utility. Studies emphasize the importance of placement as exactly as possible at the affected nerve root. Intraoperative CT guidance is considered necessary in cases where more than one level is to be treated.

The application of mobile CT, patient and image registration, and robotic guidance into the performance of nerve root infiltration will increase the accuracy and effectiveness of the procedure. Mobile CT will ensure that critical structures are avoided and confirm that the target has been obtained before injection. Patient and image registration with spine tracking will permit pre operative path planning and precise targeting. Finally, use of the robot to orient and drive the needle under physician direction will ensure the highest degree of accuracy and steadiness.

D. Transjugular Intrahepatic Portosystemic Shunt (TIPS)

Transjugular intrahepatic portosystemic shunt (TIPS) creation is an increasingly important therapy in the management of portal hypertension[71]. In this procedure, a shunt is created between a hepatic vein and a portal vein, which is structurally supported by a metallic stent. This communication between the portal and systemic venous systems allows reduction of portal pressure and amelioration of the ascites, variceal bleeding, hepatopulmonary syndrome and other symptoms associated with portal hypertension[72].

TIPS creation can be a time consuming and technically challenging procedure. As typically performed, the shunt is created percutaneously from an internal jugular vein access. The hepatic vein to be employed is selected by standard catheterization. The target portal vein can be identified and targeted by several techniques including wedged hepatic veinography using markers in the portal vein. Most often, however, the portal vein is successfully punctured after several blind passes with the Colapinto or similar needle. In difficult cases, this blind approach requires fluoroscopic exposure of over an hour to the patient[72] and increases the likelihood of an errant transcapsular puncture[73, 74]. Hemoperitoneum is reported in 2-6% of cases, with a much higher rate in inexperienced operators[75].

Our preliminary experience suggests that preoperative CT imaging can be used to plan and guide a TIPS procedure from an anterior percutaneous approach. Placement of the shunt via this anterior approach requires modification of the TIPS procedure. Following simultaneous puncture of the target portal and hepatic veins, a guidewire can be passed from the portal through the hepatic vein. A catheter would be introduced in a retrograde fashion over the guidewire and slowly withdrawn under fluoroscopic guidance until the hepatic vein lumen is entered (catheter pullback technique). The catheter is then advanced into the hepatic vein, creating a successful portal-to-hepatic vein tract. Successful TIPS creation using this technique has been demonstrated in an ex vivo porcine model.

Our proposed version of the TIPS procedure relies on pre and intraoperative CT to plan percutaneous access to the target veins. Using a 3D reconstruction of these images, the physician can determine an entry site with unobstructed access to the hepatic and portal veins. This path information, the preoperative CT, and the robot-guided instrument will be registered to patient anatomy using optical tracking technology and intraoperative imaging. The predetermined path plan will be transmitted to the robot, which can then, under physician control, obtain the hepatic and portal targets smoothly, precisely, and quickly.

This novel, anterior percutaneous approach to TIPS creation has several advantages. First, the risk of capsular puncture and intraabdominal hemorrhage due to blind puncture is minimized. There is less trauma to hepatic tissue overall because fewer puncture attempts will be required. Finally, radiation exposure to the patient and physician is minimized.

VI. SUMMARY

A program plan to advance the state of the art in image-guided, minimally invasive spine procedures has been presented. The plan includes technology developments and clinical investigations. The goal of the program is to give the physician as much information as possible about the underlying anatomy, so the procedures can be successfully carried out through small incisions with minimal trauma to the patient.

This paper described some technology developments to improve the state of the art in image-guided and minimally invasive spine procedures. The importance of a strong collaboration between technical and clinical personnel cannot be overemphasized. Through teamwork, we believe this technology can improve clinical practice and lead to better patient care.

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10.2.4 Cleary 2001b: CT-directed robot biopsy ...

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CT-Directed Robotic Biopsy Testbed: Motivation and Concept

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ABSTRACT

As a demonstration platform, we are developing a robotic biopsy testbed incorporating a mobile CT scanner, a small "needle driver" robot, and an optical localizer. This testbed will be used to compare robotically assisted biopsy to the current manual technique, and allow us to investigate software architectures for integrating multiple medical devices. This is a collaboration between engineers and physicians from three universities and a commercial vendor. In this paper we describe the CT-directed biopsy technique, review some other biopsy systems including passive and semi-autonomous devices, describe our testbed components, and present our software architecture. This testbed is a first step in developing the image-guided, robotically assisted, physician directed, biopsy systems of the future.

Keywords: biopsy, medical robotics, software architecture

1. INTRODUCTION AND OVERALL CONCEPT

Biopsy is a common procedure in the medical field. While in most cases this procedure can be completed without difficulty, there are limitations to the accuracy obtainable using freehand techniques. In addition, CT-directed biopsy can be tedious and time consuming, since frequent re-imaging may be required.

For these reasons, we are developing a robotic biopsy testbed incorporating a mobile CT scanner, a small "needle driver" robot, and an optical localizer. A system diagram is shown in Figure 1 (all figures are at the end of the paper).

The goals of the testbed are to:

1. Develop a demonstration system for robotically assisted biopsy
2. Compare robotically assisted biopsy to the current manual technique
3. Serve as a testbed for investigating software architectures for incorporating multiple medical devices

This testbed is part of a collaboration between Georgetown and the Urology Robotics Laboratory (URobotics Lab) of the Johns Hopkins Medical Institutions (http://urology.jhu.edu/urobotics/) and the Computer Integrated Surgical Systems and Technology Center (http://cisstweb.cs.jhu.edu/web/) centered at the Johns Hopkins University. As part of this collaboration, we are also planning to apply the needle driver robot to percutaneous spine procedures such as nerve and facet blocks [1].

The remainder of the paper is organized as follows. The biopsy task is described in Section 2. In Section 3, related devices for mechanically guided biopsy are reviewed. The system components for our testbed are described in Section 4. The software design is presented in Section 5.

2. BIOPSY PROCEDURE

This procedure requires a computed tomography (CT) scanner and trained technologist; a special biopsy needle; and a "biopsy tray" with appropriate syringes, needles, anesthetic solution, and sterile towels [2, 3]. It should not be performed (unless absolutely necessary) on patients with bleeding disorders or otherwise at high risk for hemorrhage.

Each patient receives a pre-procedure CT scan to ascertain the lesion site, and to determine the safest route of approach to the lesion. Once the target and the skin entry point are chosen, the skin site is marked with a radiopaque label (such as a BB or a

small needle taped to the skin). An additional axial CT image of this site is then obtained to confirm the coordinates, and calculate the desired distance from skin to target. The chosen trajectory should avoid (if possible) approaching pleura, peritoneum, or major vessels or nerves.

The entry site is then prepped with a sterile skin cleaning agent (such as povidone iodine solution), and draped with sterile towels. Local anesthetic (lidocaine HCl 1% and/or bupivacaine HCl 0.25-0.5%) is infiltrated into the entry site using a 5 or 10 cc syringe with a 25- or 30-gauge needle. After initial superficial anesthesia is achieved, the anesthetic solution may be injected deeper along the proposed biopsy track using a longer, slightly wider needle (such as a 16- to 22- gauge spinal needle). In spine biopsy procedures, care is taken to anesthetize down to and including the periosteum.

At this point, a spinal needle is inserted partially along the biopsy track, and a CT image is taken to confirm proper site and trajectory. If unsatisfactory, the spinal needle is repositioned, and additional images obtained. If adequate, the needle is advanced the rest of the way, and target acquisition is confirmed with another CT image. If the patient reports radicular pain during the needle placement, the needle is redirected; if further attempts also elicit pain, a new entry site, trajectory, and/or target may need to be selected.

Once a satisfactory angle of approach is confirmed, the spinal needle is removed, and the larger biopsy needle is carefully inserted along the same tissue path. A final CT image is obtained to confirm that the needle tip is in the target tissue before any samples are taken. Pressure is applied to the biopsy needle, along with a twisting or cutting motion (depending on the type of biopsy needle used; the recommended technique is described in the manufacturer's instructions). Before the core of tissue is removed, another CT slice is taken.

While one tissue core may suffice, many investigators take two or three samples to help ensure an adequate yield. Some may choose to have a surgical pathologist or cytologist on hand to examine the tissue specimen for suitability.

Once enough tissue has been obtained, some investigators obtain one last CT image following needle removal to demonstrate the biopsy defect in the target tissue. Direct pressure may be held on the skin entry site for several minutes to aid hemostasis, if needed.

3. LITERATURE REVIEW: MECHANICALLY GUIDED BIOPSY

Other researchers have developed robotic systems to aid in biopsy tasks. These include passive positioning systems, which provide image guidance to assist the physician in orienting the biopsy, as well as semi-autonomous robots which position, drive, and guide the biopsy needle under remote physician control.

The PinPoint™ system, developed by Marconi Medical Systems (Cleveland, OH, formerly Picker), is representative of the passive robotic biopsy assistant type [4]. PinPoint is a frameless stereotactic arm for use in planning CT-guided biopsy (Figure 2a). The arm is direction encoded so that the intervention path can be visualized on CT and evaluated. Once the optimum biopsy needle path is determined, the Pinpoint arm can be locked into place to serve as a stationary guide to needle placement (Figure 2b).

Semi-autonomous systems have been developed for use in breast and brain tissue biopsy. The Mammotome®, manufactured by Ethicon Endo Inc (Cincinnati, OH) a Johnson and Johnson Company, and the Advanced Breast Biopsy Instrumentation (ABBI®) system, a product of the United States Surgical Corporation (Norwalk, CT), are two widely available breast biopsy systems. Both systems allow remote, image-guided placement and manipulation of the biopsy tool.

The Mammotome breast biopsy system is composed of a thin probe attached to a motorized unit and an integrated vacuum source [5]. Under local anesthesia, the biopsy probe is introduced through a ¼"inch incision. The probe is navigated under image guidance to the target selected by the physician. Both CT and ultrasound guidance are compatible with the Mammotome. Once in position, a vacuum system draws tissue into the probe core and harvests small samples. The operator can navigate the probe to more than one target per insertion, allowing wide sampling from only one access point [6].

The ABBI system, allows stereotactically guided, mechanically driven fine needle biopsy and a novel "core needle" breast biopsy [7]. Rather than harvesting microhistological specimens from a variety of locations in the breast, the "core needle" breast biopsy option removes a single, solid specimen, which can vary in size from 5 mm to 20 mm, depending on physician preference. There is some evidence that one-piece cytologic specimens can aid in the diagnosis of certain breast disorders, an advantage of the ABBI core needle biopsy. Studies comparing the effectiveness of the ABBI core needle biopsy to the Mammotome's microhistological approach are ongoing [8]. Because the ABBI core needle system has the potential to remove large pieces of target tissue under physician guidance, it has potential as a treatment modality in addition to a biopsy tool. This application is still under investigation.

Two representative semi-autonomous neurosurgical biopsy systems include the Minerva, developed by the Laboratory of Microengineering at the Swiss Federal Institute of Technology in Lausanne, Switzerland, and the NeuroMate™, manufactured by Integrated Surgical Systems (Davis, CA).

Minerva is a CT guided, multi-function neurosurgical robot [9]. It operates inside a CT gantry with free longitudinal movement allowing cranial scans at any level. Under the physician's remote control, the Minerva robot can manipulate two stereotactic instruments in addition to the tool for automatic penetration of the skin, skull, and meninges. This allows the Minerva to perform a complete stereotactic procedure without physical intervention by the physician. In addition to biopsy, this system has been used for deposition of living encapsulated cells, electrode implantation, placement of radioactive sources, electrostimulation, and tissue aspiration [10].

The NeuroMate stereotactic surgical system was originally developed at the University of Grenoble, France [11, 12] and is now available from ISS. NeuroMate is an image-directed robotic assistant for frameless stereotactic neurosurgical applications (Figure 3). It can function to orient and position surgical instruments under image guidance. Much like Minerva, it is also capable of carrying out surgical procedures under remote physician control.

4. SYSTEM DESCRIPTION AND COMPONENTS

The testbed components (Figure 1) are described in the following sub-sections.

4.1 Mobile CT Scanner

The Tomoscan M is a mobile CT scanner (Philips Medical Systems, Eindhoven, Netherlands) that is easily transportable within the hospital. The system has three components including a gantry, CT table, and operator's workstation. The gantry aperture is 60 cm with a maximal field of view of 460 mm. Both the gantry and the CT table can translate, 35 cm and 150 cm respectively. The images have a resolution of 512 by 512 pixels and can be transferred to other systems using the digital imaging and communications in medicine (DICOM) standard. Protocols for cervical, thoracic, and lumbar spine exist with slice thickness options of 2, 3, 5, and 10 mm. The system has a tube voltage of 130 kV and uses a relatively low tube current between 10 and 50 mA, thereby minimizing dose exposure.

4.2 The Robotic System

The robotic system will be based on the PAKY-RCM (**P**ercutaneous **A**ccess to the **K**idne**Y** - **R**emote **C**enter of **M**otion) robot that has been initially developed at Johns Hopkins for percutaneous access of the renal collecting system [13, 14]. The robot, schematically represented in Figure 4, consists of a passive positioning and supporting arm (The GREY Arm) [15], an active remote center of motion orientation mechanism (RCM), and a radiolucent needle driver (PAKY). The device will be mounted over the CT table using a bridge fixture as depicted in Figure 4.

The overall system comprises eleven degrees of freedom (DOF). The first eight DOF are used for the initial positioning of the robot in close proximity of the skin insertion site and firmly locked during the operation. The remaining three DOF, implemented by the RCM robot and PAKY needle driver, are sufficient for orienting and inserting the needle at the desired target through the preset skin insertion point. The main advantage of this minimal kinematic architecture is the inherent safety given by the restricted mobility of the mechanical components. Moreover, separating the kinematics of the orientation and needle insertion yields decoupled needle motion capabilities, thus improving safety.

The needle driver is constructed of acrylic plastic which is radiolucent and easy to manufacture as a sterile disposable part. Driver radiolucency is essential in image-guided procedures for providing unimpeded target visualization. Whereas the driver is sterilized, in clinical use the additional components of the system in close proximity of the operation site are covered with a sterile bag.

The robot accommodates joystick control for simple maneuvers and full computer control for the actual image-guided procedure. The electronic circuitry will be fully enclosed in the supporting bridge of the arm, so that the robot is self-contained and only requires a DC power supply.

The complete system is presently under development. The new design incorporates a major improvement over the first generations of the RCM robot, the "Ball-Worm Transmission" recently developed at the Hopkins URobotics Lab. This transmission fulfills the need for implementing a simple and small no-backlash (no play between the input and output shafts) rotational transmission for miniature surgical robotics. With this addition the RCM exhibits superior motion tracking and positioning capabilities.

4.3 Localizer

The optical localizing system (Hybrid Polaris, Northern Digital, Waterloo, Canada) is used to determine the orientation and position of tracked objects relative to the camera system. Objects are tracked by rigidly attaching retro-reflective spheres or active infrared LED's (IREDs). The spheres or IREDs can be detected by the camera system and used to determine the location and orientation of the object. This version of the Polaris can track up to 3 active and 3 passive tools simultaneously and is controlled via the serial port of the host computer.

By applying reflective spheres directly to the table, we are able to track the CT table and gantry. Similarly, tracking spheres located on the robot and end-effector will enable us to directly monitor the robot position. This is especially important as a safety feature in order to verify the robot's own encoders. Finally, a dynamic reference base (DRB) tracker applied to the

patient will enable us to dynamically reference the patient compensating for patient movement or providing a warning when motion occurs. The optimum use for the localizer is still under discussion, but additional uses include robot calibration upon start-up, and assistance in marking the biopsy entry point.

4.4 Biopsy Scenario

The scenario envisioned for robotic spine biopsy is as follows:

1. The patient is positioned on the table and a series of axial scans are obtained
2. The scans are transferred from the operator's workstation to the CT workstation over an Ethernet connection using the DICOM protocol
3. The user interface software allows the physician to select the axial scan of interest and the region to be biopsied (entry location and target point)
4. The entry location for the biopsy is marked on the patient's skin (using the laser lights on the scanner and measuring off the centerline as necessary)
5. The robot is manually positioned at the skin entry point
6. The robot automatically orients the needle and inserts it
7. A CT scan is obtained to verify the needle position
8. The biopsy sample is taken

The testbed will be verified on phantoms and cadavers before any clinical trials are planned. The initial goal is to evaluate the accuracy obtainable using robotically assisted biopsy as compared to the current manual technique as described in Section 2. The interventional phantom shown in Figure 5 will be used in these initial studies.

5. SYSTEM SOFTWARE DESIGN

Current software systems deployed in surgical environments do not lend themselves to open software architectures that utilize off-the-shelf (OTS) components. These systems are developed from a single functional perspective; even if multiple functional capabilities are integrated, they are tightly integrated in a closed fashion that results in large, costly, monolithic systems. It then becomes difficult to integrate these systems with systems dedicated to other functional areas. An example of this is the need to offload images from the CT workstation to the NT workstation in our testbed environment (see Figure 1). A more desirable approach is to view technology integration via open software architectures, where various hardware and software components may be integrated on top of a common software "bus".

Our approach to integrating the hardware and software components of the robotic biopsy testbed is to develop functional component wrappers for each component and integrate them on top of an open architecture. The "wrappers" will shield implementation details from other components, reducing "hardcoded" dependencies between components and enabling the dynamic composition of functionality to meet application requirements. At the same time, the architecture must support drill-down optimizations, fault tolerance, and error handling, to ensure the complex requirements of the application domain are met. To provide a clearer picture of how these components may interact to support the robotic biopsy application, we describe component collaborations using the Unified Modeling Language (UML) collaboration diagram shown in Figure 6.

This figure shows the collaboration between high-level software components, hardware components, and the physician. Although UML collaboration diagrams are typically reserved for software components, we find this a useful notation for expressing workflows between hardware and software components, as well as indicating the role of operator intervention. Steps are numbered according to the sequence in which they are performed. This diagram shows that the CT workstation first acquires a study of images from the Mobile CT. The scans are then sent to the NT workstation, and path planning is done to determine the slice and planned path to the lesion. The NT workstation tells the Optical Localizer to track objects in the application space, which is done continuously for the rest of the procedure. The Mobile CT and PAKY-RCM robot are then positioned manually by the physician. The NT workstation then orients the needle by transmitting path and coordinate information to the robot, and the needle is driven to the target. A verification scan is then taken.

The figure shows at a high level the interactions that must take place between components. Each interaction will in fact be realized at a lower level as a number of messages sent between objects in the environment. In order to facilitate the interactions between components, the architecture must provide some common services to tie the components together. Such services include DICOM communication (CT and NT workstations), task synchronization, asynchronous and synchronous communication, error handling and event notification, logging, coordinate transformations, and redundant verification (between the localizer, mobile CT, and robotic device). An important, domain-specific example is the mapping of coordinate systems between the optical tracker, NT user interface software, and the robot. This integration task requires a precise mapping of the relative coordinate systems of each component in order to carry out visualization and verification tasks in the application space.

The current architecture is being developed in C++ using DICOM as the image transfer protocol and communication with hardware components via wrapper libraries that talk with specific interfaces (such as serial ports or special-purpose device cards). All component wrappers are being developed with well-defined object interfaces. We view this as a first step towards a more general, open software architecture where hardware and software components are integrated and configured dynamically to meet the requirements of families of surgical applications [16]. We are currently evaluating state-of-the-art middleware technologies such as CORBA, DCOM, and Jini for this purpose.

6. CONCLUSIONS

This paper described an ongoing project in developing a robotic biopsy testbed. Once the system is integrated, it will be used to compare robotically assisted biopsy to the current manual technique. This will require the continued close cooperation between the engineers and physicians and the development of appropriate measures to judge the success of the procedure.

ACKNOWLEDGEMENTS

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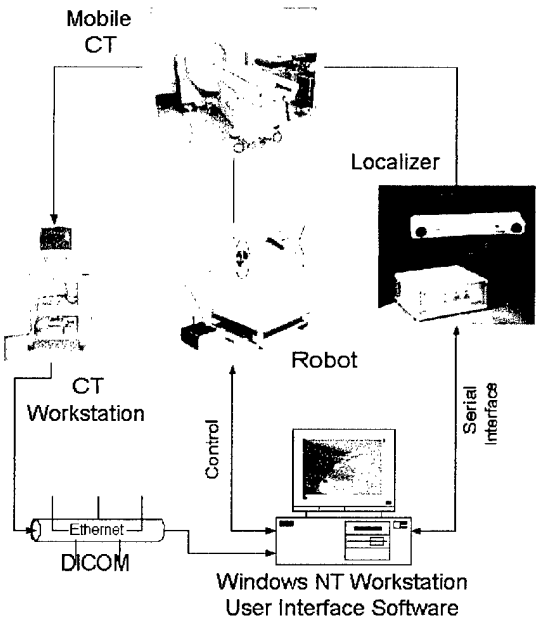

Figure 1. Testbed components

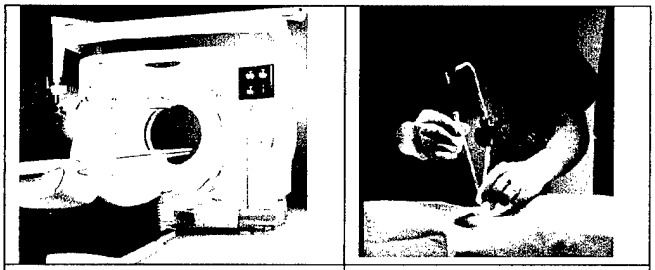

Figure 2a. Pinpoint™ arm (upper left) and CT/fluoroscopy system

Figure 2b. Pinpoint™ arm locked in place to serve as a needle guide

(Courtesy of Marconi Medical Systems: www.picker.com/ct/ctro/ctrovenuc.html)

Figure 3. NeuroMate™ robotic assistant for neurosurgical stereotactic applications
(Courtesy of Integrated Surgical Systems: www.robodoc.com/products/neuromate.html)

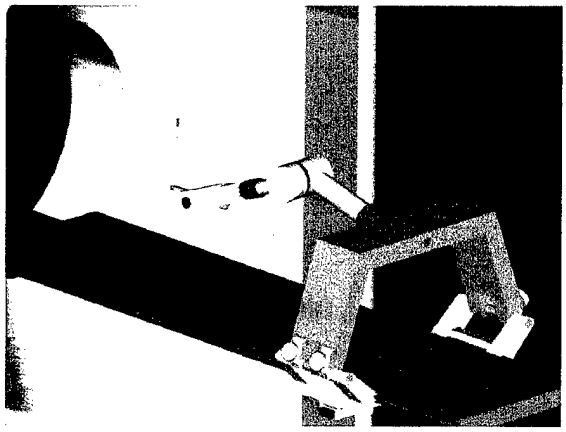

Figure 4. PAKY-RCM robot and bridge fixture

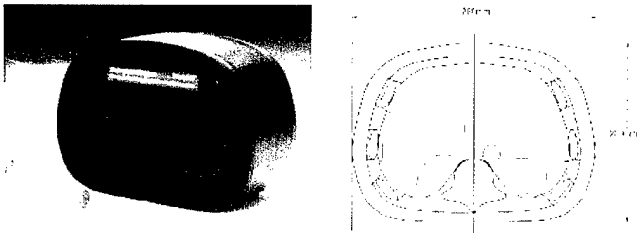

Figure 5. Interventional phantom
(Courtesy of CIRS, Inc. www.cirsinc.com)

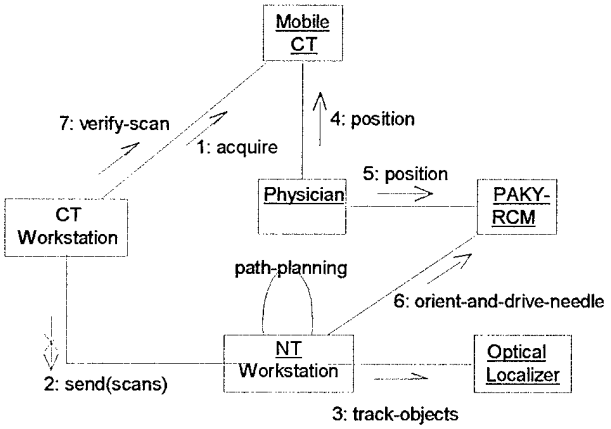

Figure 6. Testbed component collaboration diagram

10.2.5 Cleary 2000a: Robotics for percutaneous ...

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Robotics for Percutaneous Spinal Procedures: Initial Report

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Robotics were introduced into the surgical arena in the 1980's with the primary purpose of improving precision. Intracranial neurosurgical procedures were a major focus of the first robotic systems, in part because a high degree of precision is required for localization and manipulation within the brain, and because cranial anatomy provided relatively fixed landmarks. Medical robotics has since expanded to other clinical applications. Many prototype robotic systems have been developed, but presently only a few systems are available commercially. This paper presents a brief review of some developments in medical robotics, followed by a description of our research developments for robotically assisted spine procedures. The general steps in needle placement for percutaneous spine procedures are described, along with one specific procedure of interest (vertebroplasty).

1. MEDICAL ROBOTICS REVIEW

Many different research groups have developed prototype robotic systems for many different clinical applications. Some representative research groups and application areas in the United States are: 1) Johns Hopkins University in Baltimore, where a robot for percutaneous renal access [1] and a "steady hand" robot [2] for eye microsurgery and other applications are being developed; and 2) Carnegie Mellon University and Shadyside Hospital in Pittsburgh, where the clinical focus is on orthopedic applications [3]. In Europe, representative groups include: 1) Imperial College in London, England, where special robots for prostate [4] and knee operations [5] have been developed; 2) the TIMC-IMAG group in Grenoble, France, with a recent project on robotic pericardial punctures [6]; and 3) Charite Hospital in Berlin, Germany, where one focus area is maxiofacial applications [7]. In Asia, at Tokyo University in Japan, a biopsy robot for neurosurgical applications has been developed [8].

Commercial robotic systems include the ROBODOC® System for hip replacement surgery [9] and the NeuroMate ™ robotic arm for stereotactic brain surgery, both from

Integrated Surgical Systems (http://www.robodoc.com/). Perhaps the most successful commercial medical robotic device to date has been the Automated Endoscopic System for Optimal Positioning (AESOP), which is a robotic laproscopic camera holder from Computer Motion (http://www.robodoc.com/) that has been used in many clinical areas, including urological laparoscopic surgery [10]. Recently, two telesurgical robotic systems for minimally invasive surgery have been introduced which are aimed at restoring the dexterity that is lost when using traditional laproscopic instruments. The initial clinical focus for both these systems is cardiovascular procedures. The Intuitive Surgical system (http://www.intusurg.com/), da Vinci™, consists of the surgeon's viewing console, a control unit, and a three-arm surgical manipulator [11]. A similar telesurgical system, Zeus™, has been developed by Computer Motion [12]. While the da Vinci system is a six degree of freedom system (plus grip motion), the Zeus system only has four degrees of freedom, but the Zeus system is more easily transported between operating rooms.

2. ROBOTICS FOR SPINAL PROCEDURES

To the best of the author's knowledge, there are no research groups specializing in robotics for spine procedures. At Georgetown University Medical Center, we are developing a system for robotically assisted percutaneous spine procedures in collaboration with the Urology Robotics Laboratory (URobotics Lab) of the Johns Hopkins Medical Institutions (http://prostate.urol.jhu.edu/research/urobotics/) and the Computer Integrated Surgical Systems and Technology Center (http://cisstweb.cs.jhu.edu/web/) of Johns Hopkins University. The system is aimed at increasing the precision and efficiency of instrument placement and manipulation during these procedures. We believe this will lead to better patient outcomes, but this remains to be seen.

The robotic device will be based on the RCM-PAKY (**R**emote **C**enter of **M**otion / **P**ercutaneous **A**ccess to the **Ki**dne**Y**) robot that has been developed at Johns Hopkins and applied to percutaneous renal procedures (Figure 1) [13]. The robotic device consists of a passive positioning and supporting arm, an active remote center of motion orientation mechanism, and a radiolucent end-effector and needle driver. The new system is under development and will requiring adapting the PAKY robot, as described in the next section.

3. PERCUTANEOUS SPINE PROCEDURES

Minimally invasive spine procedures are rapidly growing in popularity due to improved techniques and the decreased trauma to the patient. Percutaneous spine procedures are a type of minimally invasive technique in which thin, tubular, instruments are placed and then manipulated through the skin to treat a variety of spinal conditions. The procedures of interest are biopsies, facet and nerve blocks, vertebroplasty, discography, and radiofrequency and laser ablations.

Currently, percutaneous spine procedures are performed by freehand passage of instruments (such as a needle or trocar[⊕]) from the skin surface to the spine. Based on imaging modalities such as X-ray fluoroscopy and/or computed tomography, the physician identifies the skin entry point and the target thus defining the desired needle trajectory. The physician then aligns the instrument in his/her hand and partially inserts it towards the target.

[⊕] For the spine procedures of interest here, the instrument can be a trocar (thin hollow straw-like device through which other instruments including needles can later be inserted) or a needle.

The instrument is then released and the instrument position is checked with imaging to confirm proper targeting. As required, the physician may adjust the instrument in a free hand manner and then advance further. This process of "advance and check" is repeated until the instrument is adjacent to the targeted portion of the spine.

The main problem with this approach is that the unaided human system has limitations in accuracy when initially lining up the instrument and then staying on course. Additionally, when the physician lets go of the instrument the instrument often drifts or tilts away from the desired path due to gravity, which is particularly dangerous in vertebroplasty procedures (described in the next section), where a large gauge trocar is employed. An analogous non-medical example of this problem is drilling a straight hole in wood with a hand-held drill versus a bench-mounted drill press or industrial robotic system. Photographs of the neurointerventional suite showing the fluoroscopy table and a vertebroplasty procedure at Georgetown are shown in Figure 2. From the right side photograph of Figure 2, one can visualize the freehand nature of the procedure.

Our long-term goal is to develop a robotic system that is directly linked to X-ray fluoroscopy and computed tomography and helps the physician guide the instrument to the target in a more direct, precise and controllable manner. This long-term goal will be achieved through a series of increasingly complex prototypes and clinical evaluation.

In the present development stage, we will adapt the RCM-PAKY robotic system to:

1) provide a means of mounting the robot on the fluoroscopy table in the neurointerventional suite
2) modify the end-effector so that it can hold the instruments used for spine procedures and advance them through a joystick interface under the physician's direct vision and control.

4. PERCUTANEOUS VERTEBROPLASTY

In this section one of the spine procedures of interest, vertebroplasty, will be described. The general procedures are similar across most of the percutaneous spine procedures.

Percutaneous vertebroplasty uses image guidance such as fluoroscopy or CT and involves injecting polymethylmethacrylate (PMMA, or bone cement) into the vertebral body [14]. It is currently performed to strengthen vertebral bodies that have been mechanically weakened (for example, from osteoporosis or metastases), and to relieve pain from spinal fractures (both traumatic and pathologic). As its long-term efficacy and results become known and studied, vertebroplasty is becoming a proven, first-line treatment for spine disease.

This procedure is performed with the patient in a prone position (as shown in the left hand side of Figure 2 – patient is under sheet) on a fluoroscopy table. A C-arm is used for fluoroscopic localization; some investigators also employ a CT scanner for more precise needle placement, better intra-procedure evaluation of cement load, and possible extravasation [15]. Local anesthetic and monitored anesthesia care (MAC, or conscious sedation) are used.

A small skin incision is made with a #11 blade over the operative site. A 10- or 12-gauge needle (Figure 3) is inserted into the vertebral body via one of multiple approaches: in the thoracic region, a costovertebral route is often chosen, while the lumbar spine is better managed with a posterolateral approach. The trans-pedicular route may be used in both thoracic and lumbar vertebrae.

After confirmation of needle tip position with fluoroscopy or CT (Figures 4a and 4b), contrast material is injected under active fluoroscopy to ensure that the needle is not in the venous plexus (Figure 4c: vascular embolization of cement is one of the most serious complications of the procedure, and is readily avoided with this precaution). A mixture of surgical cement (usually methlymethacrylate) and a radiographic opacifying agent (barium, tantalum and/or tungsten) is then injected into the vertebral body, also under active fluoroscopy. Injection of this mixture while a pasty consistency, rather than liquid, helps further guard against intravascular migration. Injection is immediately stopped if paravertebral or epidural opacification is seen, thereby minimizing the risk of spinal cord or nerve root compression.

Most patients experience significant pain relief within 24 to 48 hours following the procedure. Exact mechanisms for pain relief are unclear. Proposed theories include: filling of vertebral microfractures; reduced intra-body movement; and damage to nerve fibers from the exothermic reaction during cement curing.

While still a "new" procedure compared to traditional, open vertebrectomy, percutaneous vertebroplasty has emerged as a powerful minimally invasive tool for treating bony spinal disease. Mobility is achieved much sooner post-operatively, and with better residual vertebral stability than with an open procedure.

Percutaneous facet and nerve blocks are another treatment modality that appears promising with these minimally invasive techniques. In these procedures, patients are positioned prone as described above for vertebroplasty. A 18-to-22-gauge spinal needle is localized to the desired facet or dorsal nerve root region with fluoroscopy, and injection of a long-acting anesthetic (such as bupivicaine) and/ or a steroid (such as celestone) is performed following confirmation of extra-vascular needle tip position. Radiofrequency ablation may also be used in this manner. Pain relief may be obtained from minutes to weeks after injection/ablation; relief, or the lack of it, may help physicians better evaluate the cause of a patient's back and limb symptoms.

5. CONCLUSIONS

While we believe robotics may increase the accuracy and efficiency by which spine instruments are placed and manipulated, the ultimate role for robotics in the spine has yet to be determined. Other potential benefits include reduced radiation exposure for the physician and the possibility of using real-time fluoroscopic imaging while advancing the instrument. In our study we plan to assess the clinical feasibility and utility of robotic spine procedures for biopsy, facet and nerve blocks, vertebroplasty, discography, and radiofrequency and laser ablations.

The usefulness of the robotic device will be evaluated both qualitatively and quantitatively. Since this is an initial feasibility study, much of the evaluation will rely on qualitative judgments by the physician as to the utility of the system. For example, was the robot helpful in accurately aligning and inserting the needle? As a quantitative measure, we will record the time it takes to align and insert the needle with the robot compared to current practice. If the feasibility study proves successful, the next step could be a randomized clinical trial of these procedures with and without the robotic device. The ultimate goal of these developments is improved patient outcomes. To this end, clinical outcome measures as well as technical ones will need to be developed.

ACKNOWLEDGEMENTS

This work was funded by U.S. Army grant DAMD17-99-1-9022. The content of this manuscript does not necessarily reflect the position or policy of the U.S. Government.

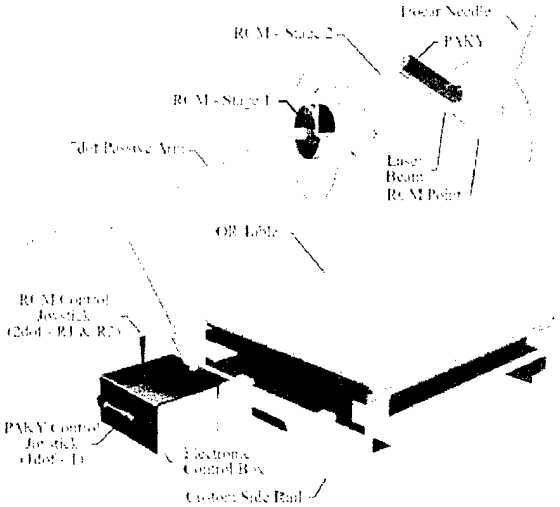
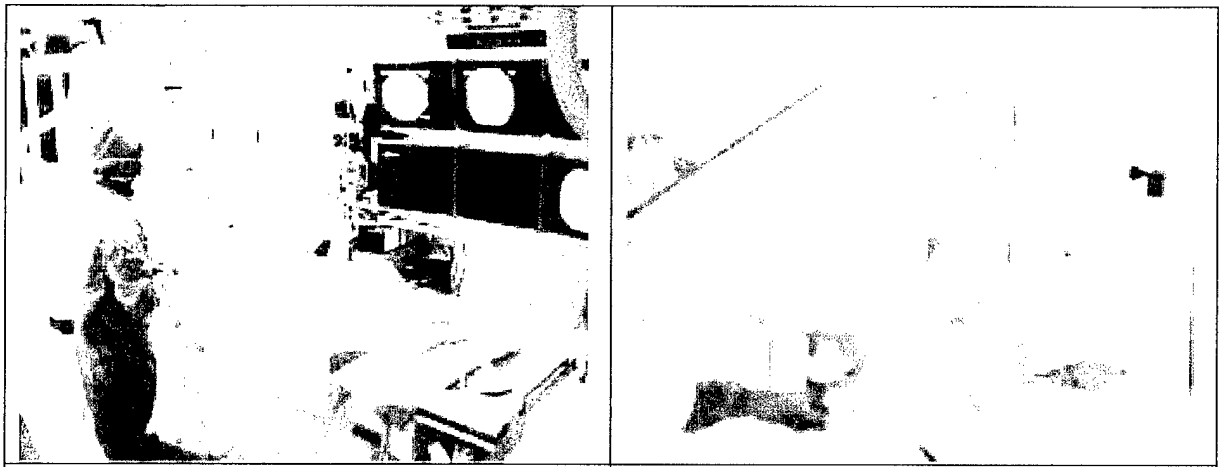


Figure 1: RCM-PAKY robotic device showing mechanical arm and joystick control (Johns Hopkins)



a) Patient prone and fluoroscopy system	b) Typical spine intervention: vertebroplasty

Figure 2: Interventional suite at Georgetown

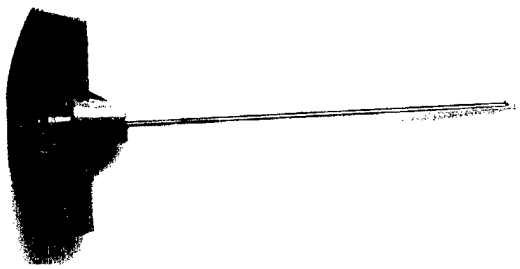
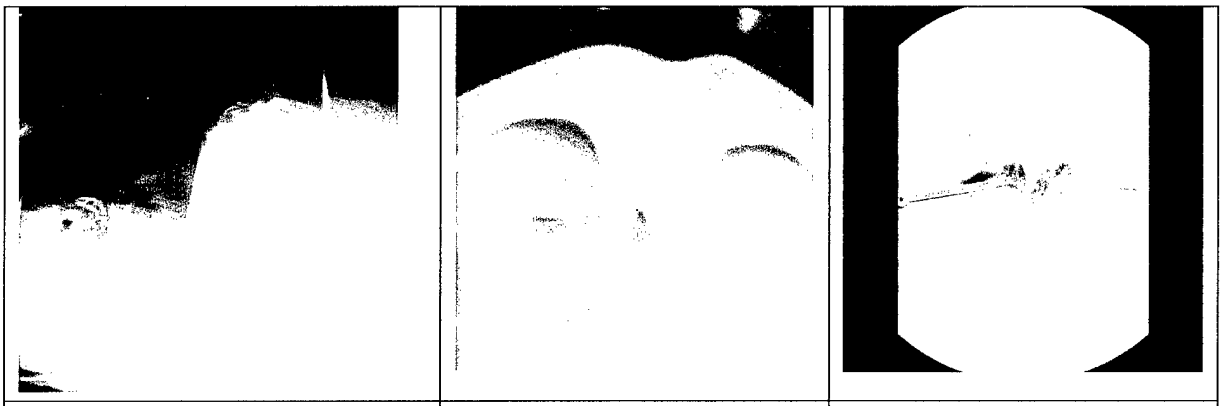


Figure 3: Vertebroplasty trocar (needle)



a) Scout CT image showing needle placement	b) Axial CT image: needle tip in vertebral body	c) Epidural venogram using contrast

Figure 4: Vertebroplasty images

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10.2.6 Cleary 2000b: Image-guided robotic ...

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Image-Guided Robotic Delivery System for Precise Placement of Therapeutic Agents

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ABSTRACT

The effectiveness of conventional solid tumor treatment is limited by the systemic toxicity and lack of specificity of chemotherapeutic agents. Present treatment modalities are frequently insufficient to eliminate competent cancer cells without exceeding the limits of toxicity to normal tissue. The coming generation of cancer therapeutics depends on the precise targeting and sustained release of antitumor agents to overcome these limitations. We are developing an image-guided, robotic system that could be applied to precise intratumoral placement of anticancer drugs and sustained release devices to advance this new treatment paradigm. The paper begins with a description of the robotic biopsy testbed concept, followed details of each of the components including a mobile CT scanner, 3D image visualization, position tracking, robotics, and software integration.

KEYWORDS: robotics, precise placement, 3D visualization, software integration, therapy

1. ROBOTIC BIOPSY TESTBED

The long-term goal of our research program is to develop an integrated system to enable the next generation of percutaneous procedures. As a first step in this effort, we are assembling a robotic biopsy testbed to serve as a platform for development and integration. The technical developments that comprise the testbed include: 1) a mobile CT scanner; 2) 3D image visualization; 3) localization (position tracking); 4) a small "needle driver" robot; and 5) software integration of the system components. In addition to providing a framework for development, the testbed will be used to compare robotically assisted biopsy to the current manual technique. A system diagram is shown in Figure 1. In this paper, we will briefly describe each of these developments.

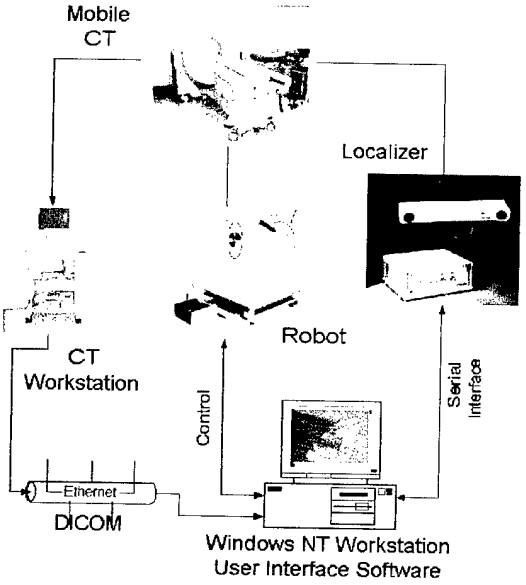

Figure 1: Robotically assisted biopsy testbed

2. MOBILE CT SCANNER

As an initial step in our research program, we have integrated a mobile CT scanner (Philips Tomoscan M) into the hospital operations to provide intraoperative images [1]. At Georgetown, the mobile CT scanner has been used in interventional radiology, the operating room, radiation medicine, the neurosurgery intensive care unit, and the pediatrics ICU. The major procedures impacted by the availability of intraoperative CT are in interventional radiology and in neurosurgery. Since May of 1998, the mobile CT has been used in over 125 procedures at our institution. Since both the gantry and the table can move during scanning, the gantry can be used with the CT table (as done in the operating room: Figure 2a) or with another table such as a fluoroscopy table (as done in the interventional suite: Figure 2b).

Figure 2a: Mobile CT in operating room during craniotomy

Figure 2b: Preparing to scan in interventional suite

3. 3D IMAGE VISUALIZATION

To demonstrate the potential of 3D image reconstruction, 3D visualization software was developed to examine the spread of bone cement after vertebroplasty procedures [2]. The images were acquired by the mobile CT scanner in the interventional suite. Off-line, these images were then transferred to a Windows NT personal computer using the digital image communications in medicine (DICOM) standard (Figure 3a). The visualization software was then used to segment the bone cement and vertebral body based on histogram windowing. The resulting images can then be rendered in 3D for viewing by the interventional radiologist (Figure 3b). To date, only a feasibility study has been completed, but the interventional radiologist has stated that the images are useful for visualizing the spread of bone cement.

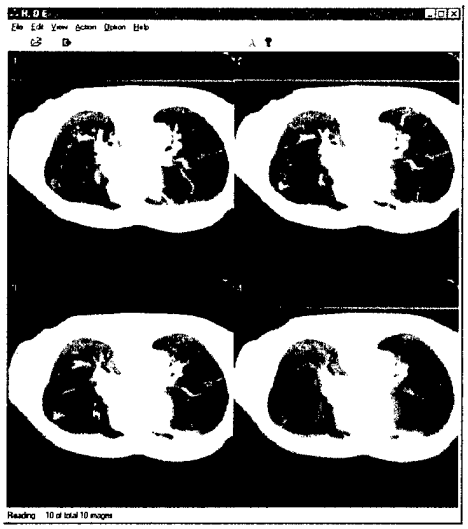

Figure 3a: Thoracic CT scans

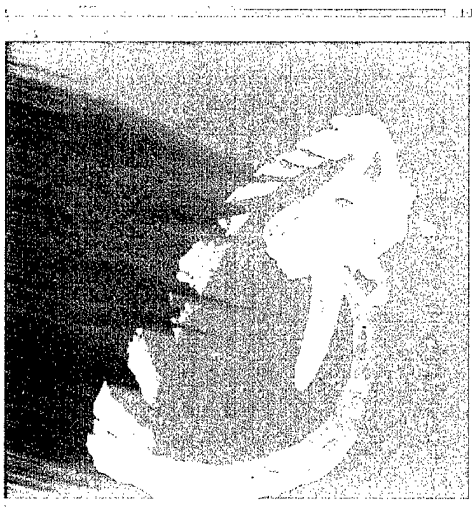

Figure 3b: 3D visualization

4. LOCALIZATION (POSITION TRACKING)

The optical localizing system (Hybrid Polaris, Northern Digital, Waterloo, Canada) is used to determine the orientation and position of tracked objects relative to the camera system. Objects are tracked by rigidly attaching retroreflective spheres or active infrared LED's (IREDs). The spheres or IREDs can be detected by the camera system and used to determine the location and orientation of the object. This version of the Polaris can track up to 3 active and 3 passive tools simultaneously and is controlled via the serial port of the host computer. In the biopsy testbed described here, we use an interventional phantom with a passive tracker rigidly attached to the spinous process (Figures 4a, 4b).

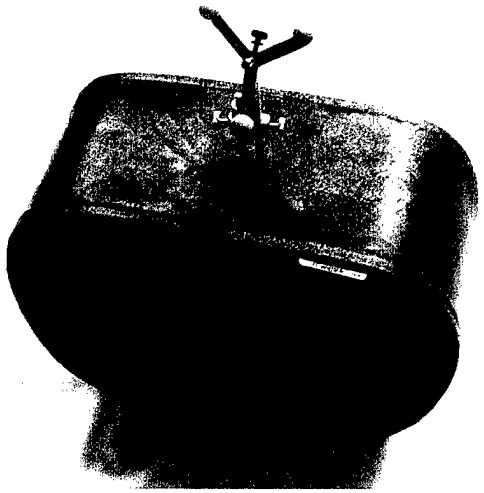

Figure 4a: Interventional phantom with passive tracker rigidly attached to spinous process

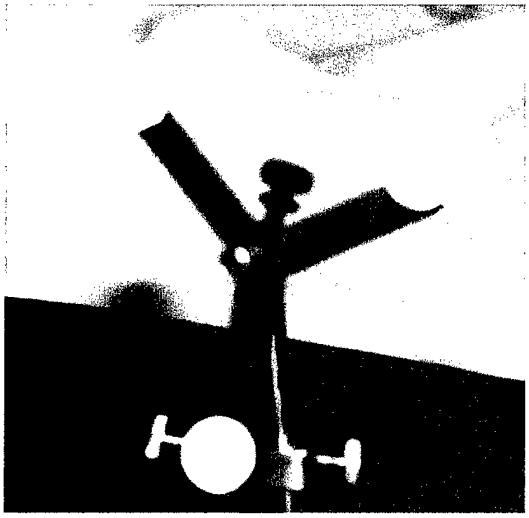

Figure 4b: Passive tracker and reflective spheres

5. "NEEDLE DRIVER" ROBOT

The robotic system is based on the PAKY-RCM (Percutaneous Access to the KidneY - Remote Center of Motion) robot developed at Johns Hopkins for percutaneous access of the renal collecting system [3, 4]. The robot, schematically represented in Figure 5a, consists of a passive positioning and supporting arm (The GREY Arm), an active remote center of motion orientation mechanism (RCM), and a radiolucent needle driver (PAKY). The device will be mounted over the CT table using a bridge fixture as depicted in Figure 5b.

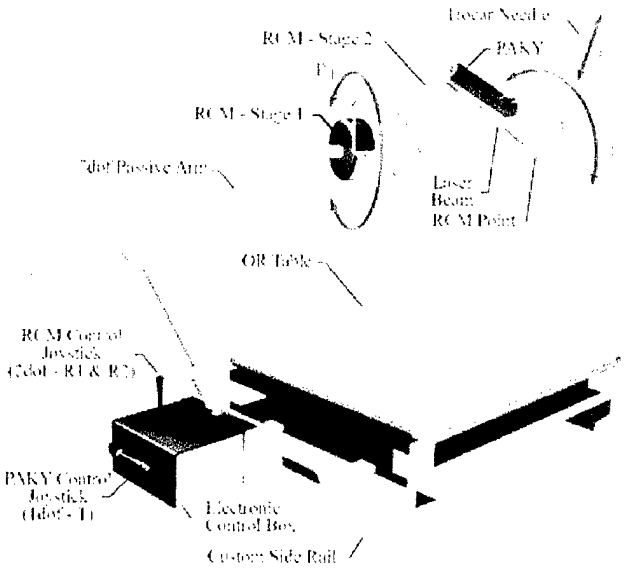

Figure 5a: Needle driver robot
Courtesy of Dan Stoianovici, PhD,
Johns Hopkins Medical Institutions

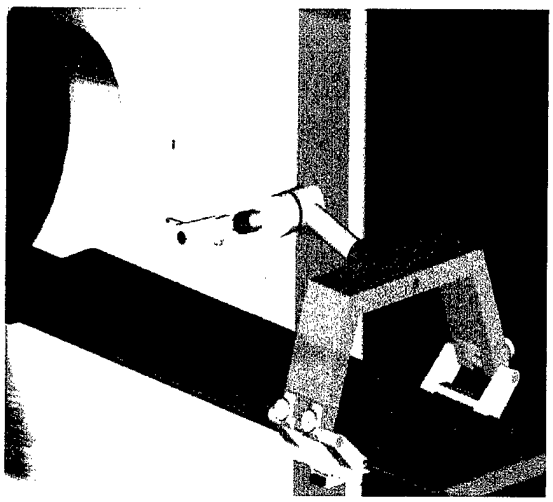

Figure 5b: PAKY-RCM robot and bridge fixture
Courtesy of Dan Stoianovici, PhD,
Johns Hopkins Medical Institutions

6. SOFTWARE INTEGRATION

Current software systems deployed in surgical environments do not lend themselves to open software architectures that utilize off-the-shelf (OTS) components. These systems are developed from a single functional perspective; it is difficult to integrate these systems with systems dedicated to other functional areas. Our approach to integrating the hardware and software components of the robotic biopsy testbed is to develop functional component wrappers for each component and integrate them on top of an open architecture. The "wrappers" will shield implementation details from other components, reducing "hardcoded" dependencies between components and enabling the dynamic composition of functionality to meet application requirements. To provide a picture of how these components may interact to support the robotic biopsy application, we describe component collaborations using the Unified Modeling Language (UML) collaboration diagram shown in Figure 6.

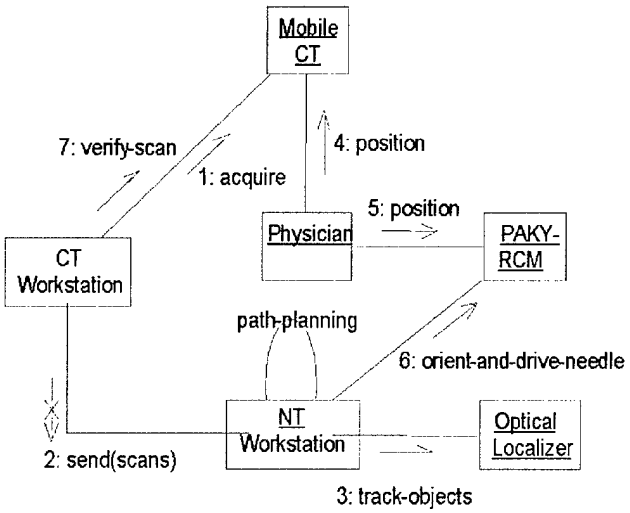

Figure 6: Testbed software component collaboration diagram

CONCLUSION

A robotic system for precise placement of needles and related instruments has been described. The system is general purpose and may be applied to many clinical scenarios. Potential advantages of the robotic delivery system are:

1. To achieve a high enough concentration, such a system may be used to precisely place chemotherapeutic agents into the site of interest.
2. Precise placement may allow a higher local concentration of these agents.
3. The system may also be used to deliver other forms of therapy including cryotherapy, thermotherapy, engineered cells, or gene transfer.
4. The system may be used to combine biopsy with treatment.

ACKNOWLEDGEMENTS

The robotic system was developed by Dan Stoianovici, PhD, and colleagues at the Urology Robotics Laboratory http://urology.jhu.edu/ at Johns Hopkins Medical Institutions. The biopsy testbed software is being developed in collaboration with Russell Taylor, PhD, and colleagues at the NSF supported Computer Integrated Surgical Systems & Technology Engineering Research Center (CISST ERC) http://cisstweb.cs.jhu.edu at Johns Hopkins University.

This work was supported by the U.S. Army under grant DAMD17-99-1-9022. The content of this poster does not necessarily reflect the position or policy of the U.S. Government.

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10.2.7 Cleary 2000c: Technical requirements for ...

Reprint begins on the next page and is 4 pages.

Technical Requirements for Image-guided Spine Procedures Workshop Summary

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Abstract

A workshop was held 17-20 April, 1999, to determine the technical requirements for image-guided procedures in the spinal column, the spinal cord, and paraspinal region. The approximately 70 Workshop participants (Figure 1) were selected on the basis of their expertise in image guidance and related fields. The Workshop consisted of plenary sessions and Working Group meetings. The six Working Groups were:

1. Operative Planning and Surgical Simulators
2. Intraprocedural Imaging and Endoscopy
3. Registration and Segmentation
4. Anatomical and Physiological Modeling
5. Surgical Instrumentation, Tooling, and Robotics
6. Systems Architecture, Integration, and User Interfaces

From the Working Group reports, the following six themes were identified:

1. Spinal disorders, especially low back pain, are a major public health problem and potentially correctable source of disability.
2. Modeling, segmentation, and registration are fundamental technical tools that still require major advances to be useful.
3. Improved image processing and display, including real-time volumetric image acquisition and three-dimensional visualization, would be extremely valuable.
4. There is a significant communication and knowledge gap between technical and clinical personnel that needs to be bridged for further advancement of the field.
5. Clinical outcomes studies, while difficult, should be pursued.
6. Infrastructure issues, including reimbursement, liability concerns, and conflicts between specialties, need to be addressed along with technical developments.

From the Working Group reports, the following six summary recommendations were compiled:

1. The development of clinically useful applications of modeling, segmentation, and registration should be supported.
2. A common and open, standard infrastructure is needed for the next generation of image-guided operating rooms or interventional suites.
3. Application testbeds are needed to ensure clinical relevance, identify potential pitfalls, and facilitate collaboration between technical and clinical personnel.
4. There are specific equipment and instrumentation needs that are required to advance the field that should be supported.
5. Multidisciplinary training and education is required.
6. A follow-up spine workshop to assess progress should be held in 2 or 3 years.

Keywords: image-guided procedures, minimally invasive procedures, spine, technical requirements

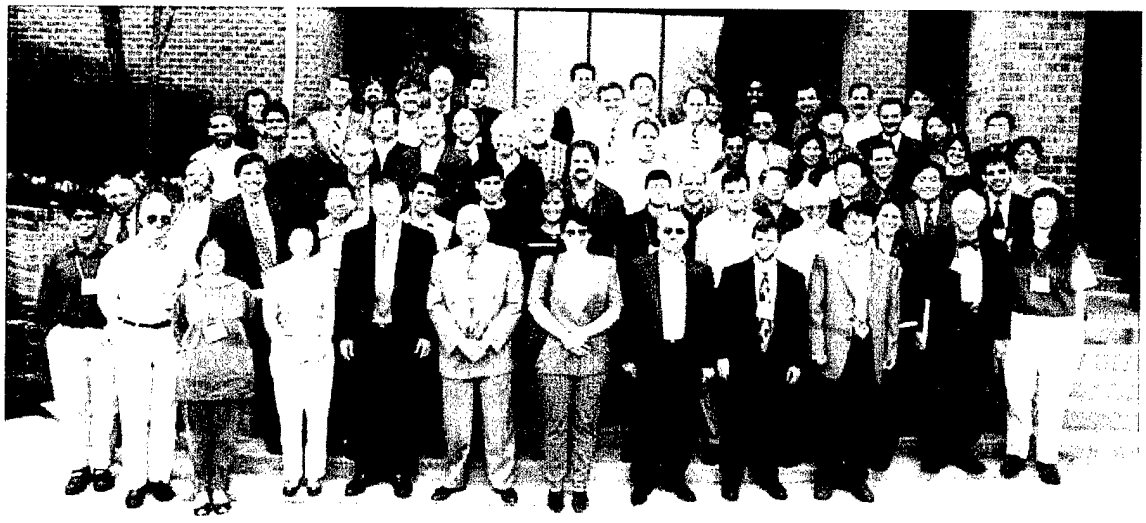

Figure 1: Workshop Participants
(Courtesy of Georgetown University Photographer)

Working Group Summaries

Working Group 1: Operative Planning and Surgical Simulators
In Working Group 1, operative planning and surgical simulators, a planner is defined as using tools, including simulation, to improve human performance on the patient-specific task at hand. A simulator is defined as an interactive virtual environment used to improve human performance. There is overlap between planning and simulation, but neither is inherently a subset of the other. The group felt that the state of the art in planning and simulation is still at a primitive stage, but the potential usefulness of planners and simulators is substantial.

The needs for image-guided spine procedures were separated into two tasks that were common to all major procedures and others that were procedure specific. The first common task is to identify the optimal trajectory for the procedure and the second is obtaining adequate anatomic perception. Procedure-specific tasks in decompression, stabilization, and deformity correction were also discussed.
Research priorities were identified, and high priority areas included task analysis and cognitive modeling, the development of high fidelity haptic interfaces, and the development of visualization and interaction algorithms for planning purposes.

Working Group 2: Intraprocedural Imaging and Endoscopy
In Working Group 2, intraprocedural imaging and endoscopy, a review of current imaging modalities for image-guided spine procedures is given. The modalities are: computed tomography, magnetic resonance imaging, X-ray fluoroscopy, ultrasound, and endoscopy. This description is followed by a list of clinical/pathological conditions judged to be candidates for image-guided spine procedures. These include degeneration of the facet or ilio-sacral joints, herniation of intervertebral discs, vertebral fracture, inflammation, and tumor resection/treatment.

The role of the various imaging modalities listed above is summarized based on whether imaging is being performed for diagnosis or therapy. Future system requirements for image-guided spine procedures are discussed in terms of preoperative imaging requirements, virtual navigation requirements, interventional guidance requirements, other design requirements, and verification of therapy/tissue status. Research needs are then prioritized, including technical challenges, infrastructure issues, and other related factors.

For technical challenges, the greatest priority need is the development of a modular concept, starting with the integration of mobile CT, fluoroscopy, endoscopy, and navigation equipment. The next greatest priority

is an open, modular, integrated MRI/fluoro-CT system for spinal work. Other priorities include increased tip accuracy and definition, multi-modality image fusion for navigation, fast volumetric 3D rendering, rapid tissue discrimination, small multi-modality endoscopic systems, the development of verification probes, and reducing the size of tomographic systems.

Working Group 3: Registration and Segmentation

Working Group 3 reported on registration and segmentation development needs. Their report begins with an overview of how image data are employed in image-guided surgery: preoperatively for planning, simulation, or model creation; intraoperatively to help guide the procedure; and a combination of preoperative and intraoperative images. Registration is then defined as the mapping of coordinates between any two spaces specifying volumetric images, the patient, or the instruments. Segmentation is defined as the delineation and labeling of image regions as distinct structures.

Clinical needs are then discussed, including requirements for accuracy and speed. Spine procedures for which image-guided surgery appears promising include instrumentation procedures, resection of tumors and arteriovenous malformations (AVMs), percutaneous procedures, the treatment of spinal instability, and, possibly, disc disease. Technical requirements are outlined in the areas of validation, registration, and segmentation.

Finally, research priorities are summarized, with the most important long-term goal being the development of intraoperative, fast, 3D imaging systems. Shorter term goals include an emphasis on validation, the development of intraoperative 3D-2D image registration methods, 3D image-patient to instrumentation registration, 3D image-to-image registration, and segmentation for various purposes.

Working Group 4: Anatomical and Physiological Modeling

This Working Group focused on issues in anatomical and physiological modeling. While modeling has many different meanings with respect to image-guided surgery, in this report the focus was on anatomical/physiological and biomechanical data sets that provide the opportunities to influence the outcomes of spine procedures. Modeling of the spine for this purpose is a formidable task that is in its infancy of development.

The most important clinical need is increased realism in the models and simulations. Technical requirements include segmentation for discriminating heterogeneous soft tissue components, soft tissue modeling, and patient-specific models.

Research priorities for model development should focus on soft tissue modeling, segmentation of heterogeneous tissue components, basic biomechanical information such as kinematics, forces, and tissue stresses, as well as the proper alignment and positioning of component parts. Physician interaction and validation studies must be a part of the evolution of the models at every stage of development.

Working Group 5: Surgical Instrumentation, Tooling, and Robotics

Working Group 5 focused on preventive care of the spine, as the aging of the U.S. population has significant implications for spine care. The largest single complaint leading to spinal interventions is low-back pain. Preventive programs will require large scale delivery of certain procedures, particularly injections, for diagnosis and treatment. It is believed that the development of special instrumentation and tooling, along with robotic systems, can contribute to the accuracy, efficiency, and safety with which such procedures can be carried out. Infrastructure needs include making visualization, registration, and data fusion standard procedures in the operating room or interventional suite. Funding for systems research and development is needed to develop and evaluate prototype delivery systems.

Working Group 6: System Architecture, Integration, and User Interfaces

Working Group 6 focused on the development of effective tools for image-guided surgery of the spine. Clinical needs include issues related to registration procedures and input of data, network requirements, graphical user interfaces, information sources, and outcomes studies. Technical requirements in imaging, including ultrasound, endoscopy, fluoroscopy, and intraoperative tomography, were identified. Technical needs in registration and intraoperative data integration were also discussed. The highest research priority

that was identified by this group was a focus on creating mechanisms for describing vertebral motion and registration accuracy via intraoperative data.

Conclusions

To date, image guidance has been driven primarily by the neurosurgery community and aimed at precise navigation in the brain. Spinal applications of image guidance have been primarily aimed at pedicle screw placement. The authors hope that this workshop is a first step in expanding the use of image guidance in the spine by identifying the relevant clinical areas, defining the technical problems, and proposing potential solutions. There are major challenges ahead, but we believe the payoff will be better spine treatments for future back pain sufferers.

Acknowledgements

The workshop was held at Turf Valley Conference Center near Baltimore, MD, from 17-20 April, 1999. The workshop was supported by the National Science Foundation (BES-9804700), the U.S. Army Medical Research and Materiel Command (DAMD17-99-1-9532), the National Institutes of Health (1R13CA81313-01), The Whitaker Foundation, and Picker International & DePuy Motech AcroMed. The workshop report is the product of many authors, and this manuscript does not necessarily reflect the position or policy of any of the funding organizations.

Special thanks are due to the workshop organizing committee and working group leaders for their contributions. The complete workshop report along with a list of participants can be found by starting at http://www.isis.georgetown.edu/ and following the links to conferences and the spine workshop.

10.2.8 Jiang 2000a: Spine biopsy simulator ...

Reprint begins on the next page and is 7 pages.

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Spine Biopsy Simulator Incorporating Force Feedback

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ABSTRACT

Percutaneous vertebral biopsy is an efficacious method for diagnosing destructive pathology of the vertebral column. However, it requires a great deal of training to become proficient. The opportunity for training is limited by the number of clinical cases requiring the procedure. The goal of the spine biopsy simulation system is to provide a realistic and safe environment for physicians to learn the procedure and improve their performance. We have developed a three-dimensional (3D) spine biopsy training system using advanced computer visualization technology and a force feedback device. The system consists of three components: an image display, a body dummy, and a force feedback device. The image display can show biopsy needle movement in both 2D computed tomography (CT) images and 3D volume rendered images in quasi-real-time. The force feedback device continuously generates resistance while the needle tip goes through tissue. Finally, an evaluation report rates the performance of the operator during the biopsy procedure. This paper will discuss the system operation, architecture and technical advances.

Keywords: *spine biopsy, simulation, force feedback, image processing*

1. Introduction

Percutaneous biopsy of the spine is a safe, effective, and reliable method for diagnosis of skeletal lesions. Needle biopsy is less expensive than an open procedure and can significantly decrease the length of hospital stay [1]. Although relatively safe, the procedure requires an experienced individual skilled in the technique and familiar with the potential complications. A physician gains the skill by intensive training and practice. Currently, this procedure is taught to residents using supervised trial-and-error on real patients. Learning to perform a spinal biopsy can be a stressful and

inefficient experience for the students and the supervisor. It can also be a painful and potentially dangerous experience for the patient. In addition, the opportunities for the residents to practice are limited by the number of clinical cases requiring this procedure.

The objective of our spine biopsy simulation system is to provide a safe and realistic training environment for the physicians to learn the procedure and improve their performance. The system is a computer-based interactive simulation system with sophisticated 3D graphics capability and integrated force feedback in quasi-real-time[1]. The system consists of three components: a high performance graphics display, a body phantom and a force feedback device. Multiple slices of axial CT images are viewable on the screen at one time, so the physician can easily select the region of interest. The system incorporates 3D volume rendering with needle insertion from selected 2D CT slices in quasi-real-time. A six degree-of-freedom force feedback device, the PHANToM® from SensAble Technology Inc., is used to simulate the resistive forces of biopsy needle insertion. The intensity of force generated by the PHANToM is determined by modeling different types of tissue to provide a realistic feeling.

The system offers a paradigm shift from traditional training by integrating technological advances:

(1) It provides a safer and more cost-effective way to learn fundamental spine biopsy techniques.
(2) It obviates the need for physical material in initial training.
(3) It provides a more accessible way for residents to practice more frequently.

Other surgical training systems have been described in the literature. A group at the Ohio State University has developed a virtual simulator for training residents in the use of regional epidural anesthesia [2]. In their case, the procedure is a single degree-of-freedom task, so the simulation haptic probe is one-dimensional. Other surgical simulation applications include intravenous catheterization [3], nasal endoscopy [4] and nerve blocks [5]. However, to the best of our knowledge, the simulator that we have developed is the only system dedicated to the spine biopsy procedure.

This paper begins with an overview of the conventional free-hand spine biopsy procedure. The training procedure on the spine biopsy simulator is described. The system architecture of the biopsy simulator is presented, followed by technical advances developed in the system. The paper concludes with a summary and future directions of research.

2. Clinical Procedure

This procedure requires a computed tomography (CT) scanner and trained technologist; a special biopsy needle; and a "biopsy tray" with appropriate syringes, needles, anesthetic solution, and sterile towels [1, 6]. It should not be performed (unless absolutely necessary) on patients with bleeding disorders or otherwise at high risk for hemorrhage.

Each patient receives a pre-procedure CT scan to ascertain the lesion site, and to determine the safest route of approach to the lesion. Once the target and the skin entry point are chosen, the skin site is marked with a radiopaque label (such as a BB or a small needle taped to the skin). An additional axial CT image of this site is then obtained to confirm the coordinates, and calculate the desired distance from skin to target. The chosen trajectory should avoid (if possible) approaching pleura, peritoneum, or major vessels or nerves.

The entry site is then prepped with a sterile skin-cleaning agent (such as povidone iodine solution), and draped with sterile towels. Local anesthetic (lidocaine HCl 1% and/or bupivacaine HCl 0.25-0.5%) is infiltrated into the entry site using a 5 or 10 cc syringe with a 25- or 30-gauge needle. After initial superficial anesthesia is achieved, the anesthetic solution may be injected deeper along the proposed biopsy track using a longer, slightly wider needle (such as a 16- to 22- gauge spinal needle). In spine biopsy procedures, care is taken to anesthetize down to and including the periosteum.

At this point, a spinal needle is inserted partially along the biopsy track, and a CT image is taken to confirm proper site and trajectory. If

[1] Quasi-real-time: The response time is within a reasonable time frame.

unsatisfactory, the spinal needle is repositioned, and additional images obtained. If adequate, the needle is advanced the rest of the way, and target acquisition is confirmed with another CT image. If the patient reports radicular pain during the needle placement, the needle is redirected; if further attempts also elicit pain, a new entry site, trajectory, and/or target may need to be selected.

Once a satisfactory angle of approach is confirmed, the spinal needle is removed, and the larger biopsy needle is carefully inserted along the same tissue path. A final CT image is obtained to confirm that the needle tip is in the target tissue before any samples are taken. Pressure is applied to the biopsy needle, along with a twisting or cutting motion (depending on the type of biopsy needle used; the recommended technique is described in the manufacturer's instructions). Before the core of tissue is removed, another CT slice is taken. While one tissue core may suffice, many investigators take two or three samples to help ensure an adequate yield. Some may choose to have a surgical pathologist or cytologist on hand to examine the tissue specimen for suitability.

Once enough tissue has been obtained, some investigators obtain one last CT image following needle removal to demonstrate the biopsy defect in the target tissue. Direct pressure may be held on the skin entry site for several minutes to aid hemostasis, if needed.

3. Simulation System Procedure

This section walks through the biopsy procedure using the simulation system. We tried to mimic the clinical procedure as close as possible. In the simulation procedure, the trainer sets up the lesion and directs the training session. The trainee performs the simulation accordingly.

Lesion Generation. This module allows lesions to be added for training purposes. In this stage, a preview image and a set of corresponding CT images are loaded into the application. The GUI is shown in Figure 1. A horizontal red line across the preview image (top half of Figure 1) indicates the position of the CT slice of interest. The corresponding CT image is shown in the bottom half of Figure 1. The trainer can move the line up and down and select the CT image in which to embed the lesion. The size of the lesion can also be selected. This functionality provides the flexibility to do different types of spine biopsy training.

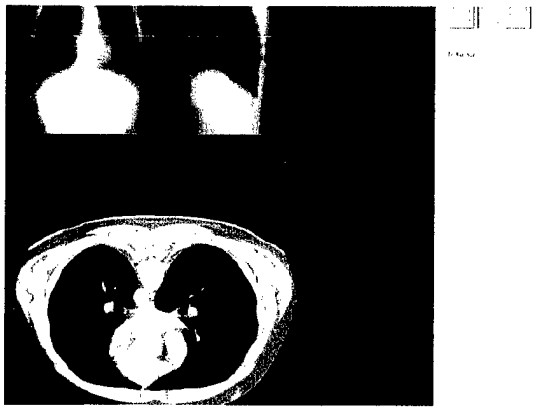

Figure 1. Lesion generation

CT Scan Review. In this stage, the trainee views all the CT images and chooses the path for the biopsy. The GUI for this stage is shown in Figure 2. First, the trainee has to select a region of interest by moving the upper limit line and lower limit line on the preview image. We assume the region includes the lesion, which is shown by a red line across the preview image. By clicking the scan button on the right panel, all the CT images within this selected region are displayed. Any slice can be zoomed in so that the trainee can carefully examine the slice of interest. The GUI can display as many as 16 slices at one time. Information of the CT scans and the patient is shown on the right as well. This stage mimics the clinical stage when the physicians reviews the CT scans.

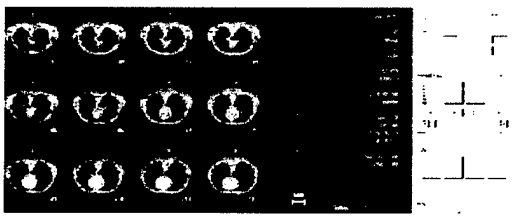

Figure 2. CT scans

Path Planning. The next step is to plan the path for the biopsy on the CT image. The program calculates the distances and angles of the path. The trainee can re-plan the path or

even go back to the previous stage, if desired. The GUI is shown in Figure 3.

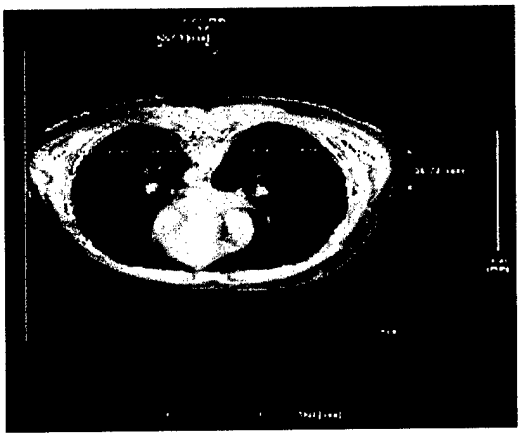

Figure 3. Path planning

Simulation. Depending on the experience of the trainee, the simulation can be done either in visual mode or blind mode. In the visual mode, three 2D images in axial, sagittal and coronal views respectively and a 3D reconstruction are provided. The planned path is shown on each of the images. Figure 4 shows the visual mode simulation. This is designed for a junior level trainee. He can visually see the movement of the needle and the path he needs to follow during the simulation. The blind mode simulation is designed for trainees who have some level of experience and want to improve their biopsy performance.

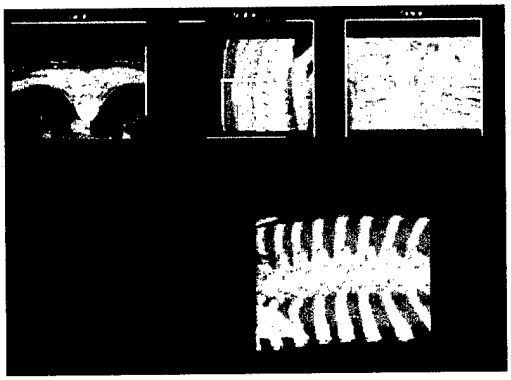

Figure 4. Visual mode simulation

In the blind mode, there are only axial and sagittal views, which mimic the real clinical situation. Moreover, the planned path is not provided. The trainee can only see the entry point he selects on the skin and the lesion. He has to make sure the needle movement is following the path in his mind. The blind mode is shown in Figure 5.

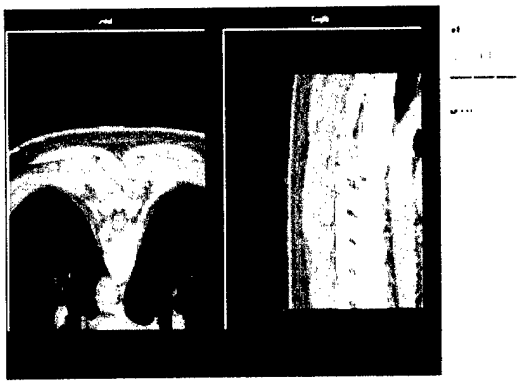

Figure 5. Blind mode simulation

The trainer must enable the PHANToM needle holder and force feedback device at its home position, so that the needle position can be tracked correctly. The system also needs to be calibrated by pointing the needle at the opening on the body dummy. The calibration data is used to match the entry point on the image display with the physical opening on the body dummy. Figure 6 shows the haptic device and body dummy on the testbed.

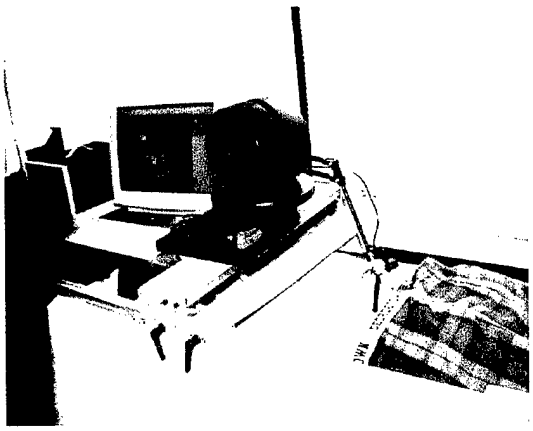

Figure 6. Computer, force feedback device, and body dummy

After the calibration, the trainee can start the needle insertion. When he moves the biopsy needle, which is attached to the PHANToM device, he can see the needle movement in the image display in quasi-real-time. Visualization

of the needle helps to keep the needle along the desired path. At the same time, the trainee also feels resistance from the PHANToM as the needle travels through different types of tissue. The trainee feels a slight "pop" as the needle punctures the skin. The resistance becomes larger as the needle goes from fat to muscle. It reaches maximum when the bone is contacted. During the simulation, the trainee is allowed to make more than one trial until he reaches the target lesion. If the trainee punctures some critical organs, a red warning box will appear to alert the trainee.

Evaluation. Finally, after the biopsy is completed, an evaluation report is given. It tells the trainer how many trials were made, how long it took him to reach the target, the final position of the needle when the biopsy ends, and a list of organs punctured during the biopsy. Furthermore, the needle route of the simulation is also displayed in the axial and sagittal view. 2D and 3D trajectories are also calculated. Based on these data, the trainer can evaluate the performance of the trainee. The simulation procedure is designed based on two principles: We want the procedure to be as close to the clinical procedure as possible. We also want to facilitate the training purpose of the system, so that some actions, which could not be carried out at a clinical setting, could be exercised on the simulation system.

4. System Architecture

The spine biopsy simulation system we developed consists of four blocks as shown in Figure 7. This configuration is typical of many other surgical simulator projects [7]. Figure 7 shows the user, the visual interface, the body dummy, and the haptic (force feedback) device.

The user interacts with the simulator by manipulating the needle, which is attached to the haptic device. The haptic device exerts force feedback to the user, which simulates the "feeling" of a biopsy on an actual patient. The visual interface displays part of the selected CT slice in three views and a 3D region of interest. When simulating the procedure, the user gets quasi-real-time visual feedback from the display and force feedback from the haptic device. The body dummy adds visual realism to the simulation and provides the anatomical model for the image display. A software module links the anatomical model to the haptic controls. The software module computes the motor torques for the haptic device based on the position input and segmentation information of the anatomical model. The motor torques are sent to the haptic device, and any updates to the anatomical model are sent to the visual interface. The haptic and visual computation can be done on different machines, depending on the system architecture.

In a typical implementation, the haptic device must be updated at a fairly high rate (1000 Hz) to ensure stability and a responsive interface. On the other hand, the visual interface can be updated at a much lower rate (30 Hz). This is because the force information changes much more rapidly and discontinuously than the position information displayed in the visual interface.

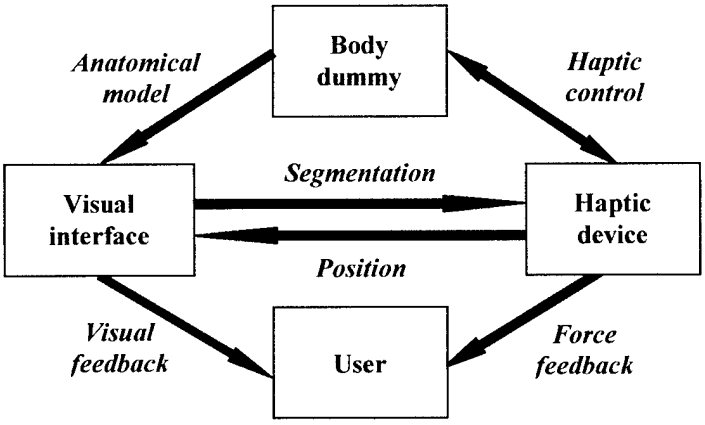

Figure 7. Spine biopsy simulation system configuration

The spine biopsy simulation system consists of the following software and hardware:

(1) System Hardware
- Processor: 450 MHz Pentium II
- RAM: 256 MB
- Hard disk: 500 MB
- Monitor resolution: full color 1024x768
- Haptic device: PHANToM® (with tracking ability)

(2) System Software
- Operating system: Windows NT 4.0
- Software toolkit: GHOST 2.1 and MFC 4.2
- Compiler: Microsoft Visual C++ V6.0
- Model representation: Volumetric modeling

5. Software Development

The software includes GUI components, image processing, and force feedback computations. The GUI components were described in the previous section. This section will focus on image processing and force feedback.

5.1 Image Processing

Several image processing techniques are implemented in the spine biopsy simulation system, including a block-based volume rendering scheme [8]. Volume rendering is a powerful tool for visualizing sampled scalar values from 3D data without fitting geometric primitives to the data [9]. However, the size of volume data is usually too big to handle in real time. The block-based volume rendering algorithm uses shear-warp factorization. The algorithm performs volume rendering by using organ segmentation information as well as 3D volume data. By using this algorithm, we can reduce storage requirements and increase the rendering speed by treating the 3D data on a block-by-block basis.

For CT image segmentation, we implemented a watershed algorithm developed by the topographic field [10]. Generally, a watershed-based segmentation algorithm has three steps: image simplification, seed extraction, and boundary decision. A proper seed extraction is very important to the segmentation quality. In the current application, we divided the CT image into 4 sub-images by windowing its gray-level histogram. Then we extracted seed areas from each sub-image according to its own characteristics. The segmentation is done off-line before the training session begins [11].

For rendering the needle in the 3D image, we combine a volume-rendered CT image and a surface-rendered needle image [12]. In general, volume rendering requires a large amount of computation and memory, hence is slower. The image update should be performed frequently enough to show the needle motion. The viewing direction for the 3D image is not changed very often, so volume rendering is suitable for displaying the CT images. For displaying the position of the needle, we use surface rendering to realize a faster image update.

5.2 Force Feedback

Realistic force feedback is critical to a realistic simulation experience. Part of the research here is to compare different force feedback models. Therefore, our system is capable of accommodating multiple force models. The user can select the desired force model at run time.

The current force feedback model calculates the magnitude of the force based on the segmentation information and the tissue type corresponding to the needle location [13]. Figure 8 shows the force profile of the force model. We assume that in each tissue type the force feedback is linear to the displacement in the tissue type. From the skin to the fat, a force "hump" is implemented to simulate the feeling of skin puncture. The intensity of the force increases while the needle goes from fat to muscle to bone. Other tissue types are ignored in this force model. In order to maintain device stability, force ramping is implemented to counter abrupt force changes. Since bone has the highest force coefficient, additional ramping is applied when needle starts to get into bone. Gravity compensation of the needle is also taken into consideration.

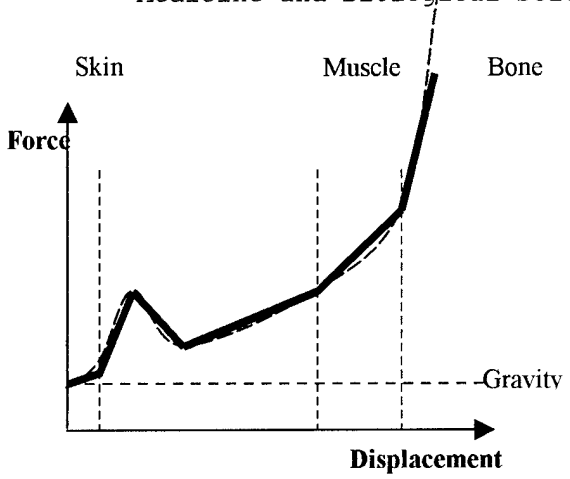

Figure 8. Force feedback model

6. Conclusion

This paper has presented a spine biopsy simulation system with 3D visualization and force feedback. The system aims at providing a safe and cost efficient platform for spine needle biopsy training. Future research directions include improvement in 3D rendering speed, experimental data analysis and tissue modeling.

Acknowledgements

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10.2.9 Jiang 2000b: Component-based technology ...

Reprint begins on the next page and is 7 pages.

International Conference on Mathematics and Engineering Techniques in Medicine and Biological Sciences, June 2000, 615-621, CSREA Press

Component-based Technology Integration for Minimally Invasive Spine Procedures

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Abstract

In several medical research groups, the concept of the high technology operating room is beginning to emerge. This is an operating room where the latest technology in imaging, instrumentation, tracking, robotics, and patient information systems is integrated to assist the surgeon in carrying out a procedure. The ultimate goal of this concept is to provide better patient care by enabling a more precise operation and minimizing surgical trauma. While pieces of the high technology operating room have begun to appear, a hardware and software framework for integrating these various hardware and software components has not yet been developed. The result is an increased cost and risk of technology introduction into surgical environments. The goal of our research effort is to propose a component-based software framework for integrating these technologies, and apply this framework to the image-guided spine procedures program already in progress at Georgetown University Medical Center. This framework is a first step towards defining common standards for integrating hardware and software components in the high technology operating room of the future. This paper will report on both the work we have completed to date and our research plan for developing the architecture.

Keywords: *software architecture, minimally invasive procedures, robotics*

1. Introduction

Technology applications in medicine are, and will be for the forseeable future, a research thrust for information technology (IT) [1]. Unfortunately, current IT research thrusts in this area center around data management applications such as patient identification and records management, or in purely functional techniques, such as advanced image processing algorithms. The integration of IT into the surgical environment introduces many difficult problems that cannot be answered today. We contend that one of the major problems is a lack of a software architecture for integrating new information technologies. An understanding of the class of software architecture appropriate to this domain will lead to reduced time and costs for industry and academic researchers alike. A component-based approach, which has been able to achieve these benefits for distributed applications in the Internet age, may be applied in this domain to achieve similar benefits. These benefits will then be transferable to domains with similar constraints on quality attributes of the software architecture. Components of the high technology operating room will include some or all of the following: intra-operative imaging, instrument tracking and image overlay, robotics or mechanical guidance, an electronic medical record including patient history, imaging studies, lab results and dictation, and

physiological monitoring (see Figure 1). The integration of these components through software brings about some unique challenges. From a software engineering perspective, the integration task requires that a clear architecture be created that allows components to be introduced into the environment with minimal risk. These risk factors constrain the software architecture space through complex requirements, such as quasi real-time performance, fault tolerance, security, and Quality of Service (QoS).

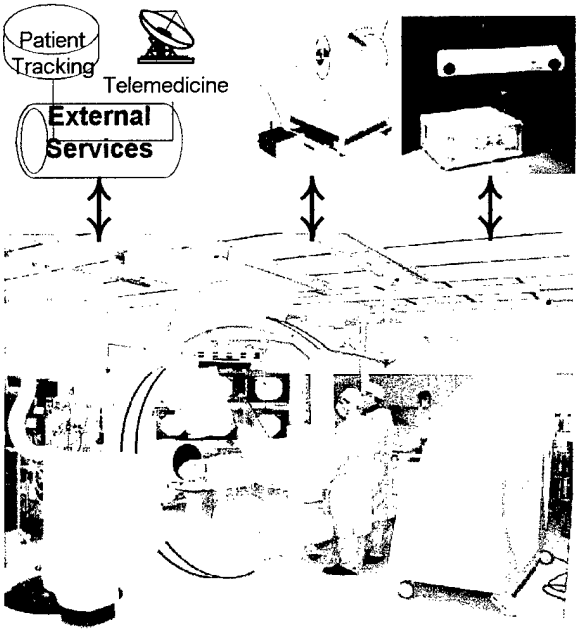

Figure 1. Surgical Suite of the Future

This paper is a report on work in progress at the ISIS Center at Georgetown University. This is a collaborative research effort between Georgetown University, The Catholic University of America, and Johns Hopkins University. We have already made progress toward our goals in several areas. In the clinical arena, a mobile CT scanner has been integrated into the interventional suite, operating room, intensive care unit, and other locations. In the interventional suite, the mobile CT is used in conjunction with bi-plane fluoroscopy for various interventions including vertebroplasty. In the technical arena, a software package has been developed under Windows NT that can receive DICOM images from various modalities including CT, MRI, and fluoroscopy. This software is a base for our technology innovations including work in image visualization and registration. A 3D visualization module has been created that can be used to examine the spread of bone cement after vertebroplasty procedures. We are in the progress of integrating an optical tracking system and a robotic needle position device with the mobile CT and visualization software components. To support our long-range goal of a general framework for technology integration, we are looking at off-the-shelf software architectures such as Java's Jini and OMG's CORBA platform.

This paper will report on both the work we have completed to date and our research plan for developing the architecture. The paper is organized as follows. Section 2 provides some background on the state of technology integration in surgical environments while Section 3 provides background on the current state of component-based software engineering (CBSE). In Section 4 we describe the architecture of our first-generation testbed, and in Section 5 we conclude with a discussion of how we will continue our research.

2. Technology Integration in Medicine

While computers are used in many areas of medicine, a software architecture for integrating advanced medical technology in the surgical suite has not yet been developed. This section discusses some of the integration standards used in medicine, and describes related research activities in industry and academia.

2.1 Software Standards in Medicine

CORBAmed is the healthcare domain task force of the object management group [OMG 1999b]. CORBAmed defines standardized interfaces to several healthcare services. Although the CORBAmed task force states one of their objectives is to promote interoperability among healthcare devices, instruments, and information systems by using CORBA technology, the only area addressed so far is healthcare information systems.

HL7 (Health Level 7) is a non-profit organization developing standards for healthcare in the domain of clinical and administrative data. The most widely used HL7 specification, the *Application Protocol for Electronic Data Exchange in Healthcare Environments*, is a messaging standard that enables disparate healthcare applications to exchange data [ANSI HL7 1997]. Note this standard addresses data exchange, but not device control.

DICOM (Digital Imaging and Communications in Medicine) is an application layer protocol for the transmission of medical images, waveforms, and ancillary information [NEMA 1999]. DICOM has been extremely successful in allowing the interchange of medical images between different vendors, but the standard does not cover device control.

2.2 Related Research

Academic research groups have focused on functional applications. For example, the Surgical Planning Laboratory at Brigham and Women's Hospital in Boston has been developing an integrated surgical suite around an interventional MRI scanner [Grimson et al. 1999]. While their main technical research area is to develop methods such as segmentation and visualization for post-processing of digital medical image data, they have also successfully integrated the MRI scanner and a tracking system with their visualization software. They are currently integrating an MR-compatible robot as well. However, this system has taken many years and man-hours to develop.

One research group that has done some related work in this area is the Computer Integrated Surgical Systems and Technology (CISST) group at Johns Hopkins University (http://cisstweb.cs.jhu.edu/web). CISST has developed a modular control library for surgical robots using a client-server architecture for incorporating robotics, tracking, and other devices in the operating room of the future.

3. CBSE for Technology Integration

Component-based software engineering (CBSE) is increasingly popular due to the explosive growth of the Internet and Object-Oriented Analysis and Design (OOA&D) over the past decade. There is now a vision of dynamic components that are described, located, and composed at run-time over the Internet to produce applications with specific behavior focused on customer needs. This vision is a significant departure from legacy software systems that were constructed as monolithic "stovepipes" (Figure 2). Component-based software systems promise increased reuse, flexibility, and maintainability compared to their legacy counterparts.

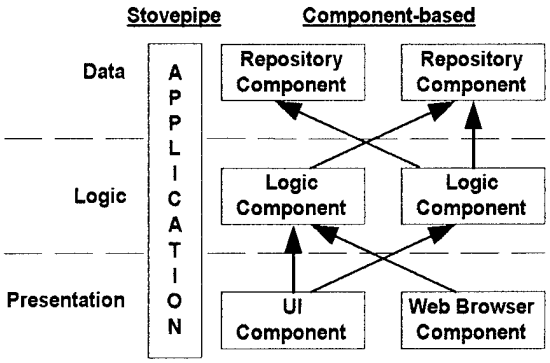

Figure 2. Software Architectures

CBSE is currently applied primarily to application domains that manipulate purely information products. Example application domains include e-commerce, workflow, inventory management, and so forth. These application domains, while often critically important to an organization's business objectives, can more naturally apply CBSE techniques than application domains with difficult to achieve requirements on real-time performance, fault tolerance, security, and QoS. There are two reasons for this difference. First, components constructed in typical application domains are, in Brooks terms [6], "infinitely malleable". That is, the component implementations, and often their interfaces, can be manipulated to rearrange responsibilities within the system. This reconfiguration cannot easily be done in domains with difficult requirements. The components in these domains often correspond to hardware devices that have specific capabilities that are not malleable through software. Second, component-based software systems are intentionally loosely

coupled, with responsibilities distributed over the set of components that comprise the entire software system. However, this is a problem since "Many computational aspects of a program spread throughout the whole program and cannot be nicely confined to a small number of runtime components." ([7]). Furthermore, in specialized domains the requirements are typically specified at the system level, and the behavior of the entire system needs to be constrained to satisfy these requirements. The issue for CBSE here is how to ensure these "global" requirements are satisfied by the set of loosely coupled components. As a corollary to this issue, there is also the problem of increased latency in a component-based architecture implementation. The loose coupling between components typically manifests itself through extra levels of indirection in the implementation, resulting in further difficulties in satisfying system-level requirements in practice.

CBSE holds great promise as the foundation for building software architectures, but for this promise to have broad impact, the benefits must be available to a broader set of application domains. These domains have the same need to produce reusable, flexible, maintainable, and evolvable software. In fact, often this need is more compelling in these domains due to the traditionally high cost of satisfying these requirements. It is our contention that more research is required to address how CBSE can be applied to application domains such as technology integration in surgical environments.

It is our belief that the benefits being reaped from the CBSE revolution can be applied to the problem of technology integration in surgical environments. We believe that the results will be a reduced cost of entry into the field for researchers and vendors alike, open platforms for robust integration, and systematic approaches to addressing system issues such as fault tolerance and quasi-real-time performance.

4. Robotic Biopsy Testbed

Pursuant to our belief that CBSE can be fruitfully applied to the task of technology integration in surgical environments, we have developed a first-generation system that integrates various hardware and software components for robot-assisted biopsy procedures. This testbed is presented in detail in an upcoming paper [8]. In this section we briefly overview the integration of the various hardware and software components. In the next section we discuss the direction this research will take toward the next generation.

4.1 Robotically-assisted biopsy procedure

We describe a needle spine biopsy procedure elsewhere in these proceedings [9], so we will not repeat the presentation in this space. We begin however, by describing the adapted testbed procedure using robotic assistance, optical tracking, mobile CT, image acquisition and selection, and image rendering.

The hardware and software components of the robotic testbed are shown in Figure 3.

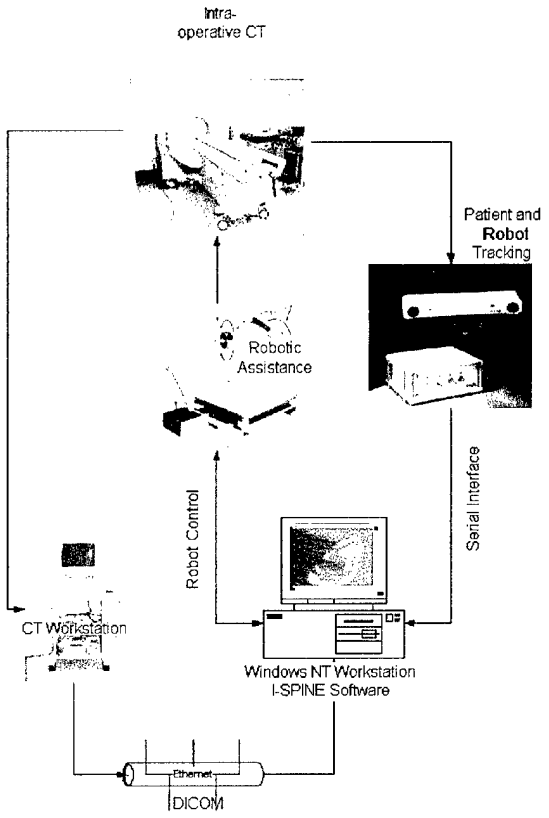

Figure 3. Robotic Biopsy Testbed

The scenario envisioned for robotic spine biopsy is as follows:

1. The patient is positioned on the table and a series of axial scans are obtained.
2. The scans are transferred from the operator's workstation to the NT workstation over an Ethernet connection and using a DICOM sender and receiver.
3. The user interface software allows the physician to select the axial scan of interest and the region to be biopsied (entry location and target point).
4. The entry location for the biopsy is marked on the patient's skin (using the laser lights on the scanner and measuring off the centerline as necessary).
5. The robot is manually positioned at the skin entry point.
6. The robot automatically orients the needle and inserts it.
7. A CT scan is obtained to verify the needle position.
8. The biopsy sample is taken.

The testbed will be verified on phantoms and cadavers before any clinical trials are performed. The initial goal is to evaluate the accuracy using robotically assisted biopsy as compared to the current manual technique.

4.2 Robotic Biopsy Components

The following sections describe each of the components in Figure 3 in detail.

4.2.1 Mobile CT Scanner

The Tomoscan M is a mobile CT scanner (Philips Medical Systems, Eindhoven, Netherlands) that is easily transportable within the hospital. The system has three components including a gantry, CT table, and operator's workstation. The gantry aperture is 60 cm with a maximal field of view of 460 mm. Both the gantry and the CT table can translate, 35 cm and 150 cm respectively. The images have a resolution of 512 by 512 pixels and can be transferred to other systems using the digital imaging and communications in medicine (DICOM) standard. Protocols for cervical, thoracic, and lumbar spine exist with slice thickness options of 2, 3, 5, and 10 mm. The system has a tube voltage of 130 kV and uses a relatively low tube current between 10 and 50 mA, thereby minimizing dose exposure.

4.2.2 Robot

The robotic device will be based on the RCM-PAKY (*R*emote *C*enter of *M*otion / *P*ercutaneous *A*ccess to the *K*idne*Y*) robot that has been developed at Johns Hopkins and applied to percutaneous renal procedures [10, 11]. The robotic device consists of a passive positioning and supporting arm, an active remote center of motion orientation mechanism, and a radiolucent end-effector and needle driver.

4.2.3 Tracker

The optical tracker is capable of determining the location of objects in space with respect to a pre-defined coordinate frame. For each object to be tracked, special reflective sensors are positioned on the object. These sensors can be detected by the optical tracker and used to determine the location of the object. The optical tracker interfaces to the NT Workstation through the serial port. ASCII commands are sent through the serial port to invoke tracker functions, and the results are returned in a similar manner. The optical tracker is the hybrid Polaris from Northern Digital (Toronto, Canada). The Polaris can track up to 3 active and 3 passive tools. We plan to track the CT table and gantry, the robot and end-effector, and the patient. The optimum use for the tracker is still under discussion, but potential applications include 1) redundant checking of the end-effector position (in addition to using the robot's encoders); 2) compensation for patient movement (or warning); 3) robot calibration upon start-up; and 4) assistance in marking the biopsy entry point.

4.2.4 I-SPINE Software

The I-Spine software component provides the graphical user interface (GUI) and image rendering software functionality. It also serves as the current integration point for all software and hardware components [12].

The GUI allows the physician to view a study of images in an NxN "up" display. When a

desired scan is selected for biopsy targeting, the physician switches to a single image view display and plans a path to the target lesion on the image, as shown in Figure 4.

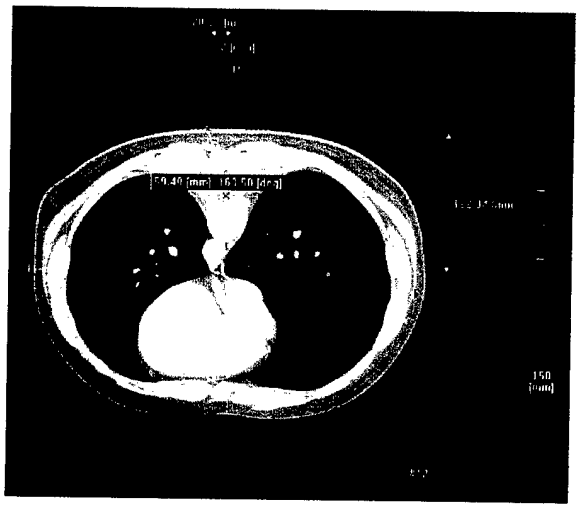

Figure 3. Lesion Targeting GUI

Currently, the I-SPINE software employs a multi-threaded design to integrate the robotic device and optical tracker. The robotic device presents information through a special motion controller card placed in the Windows NT Workstation, while the optical tracker is connected to the Workstation via a standard serial port.

With this testbed system we have been able to demonstrate the functionality of our scenario as described above. There are still many tasks to be performed however. For example, we are exploring the feasibility of attaching passive tracking fiducials to the radiolucent robotic end-effector and the biopsy needle, as well as to the CT table. This information would enable us to redundantly verify all components in image space. In addition, we are looking at ways to improve the needle positioning process. Currently the needle is manually positioned (before orientation), and we are considering modifications of the CT's laser-light position ability or the use of the optical tracker to verify needle positioning.

5. Next Generation Testbed

The first-generation testbed presented in Section 4 demonstrates our ability to integrate hardware and software components fairly easily. A closer inspection of the system architecture however, reveals potential long-term drawbacks:

- The system is not scalable.
- Performance is limited by the processing power of the single I-SPINE Workstation.
- Redundant information is available through the optical tracker, however, there is not a systematic solution to fault-tolerance.
- The adaptability of the system with respect to the introduction of new hardware and software components, or the modification of the current components, is unknown.

For these reasons we intend to apply pure CBSE practices in to the testbed. Our goal is to provide an infrastructure that is scalable, efficient, fault-tolerant, and resilient to change.

We are currently investigating two off-the-shelf (OTS) middleware products, Jini™ and CORBA™. Jini™ is an architecture that supports highly dynamic environments for networked devices. The intent of Jini™ is to allow components to join (and unjoin) from networked communities at run-time. This is a highly desirable feature in component applications, since it decouples components, providing dynamic composition capability. However, this is not a needed feature in our surgical environment. While we envision many possible component configurations in surgical suites, the configurations will be known *a priori*, and hence will not require run-time binding.

CORBA™ (Common Object Request Broker Architecture) is a set of middleware specifications maintained by the Object Management Group (OMG), a consortium of researchers, vendors, and technology users. The OMG has several specifications relevant to our research in the areas of components [13], real-time computing [14], fault tolerance [15], and embedded devices [16], but it is unclear how soon implementations will be available.

Current OTS middleware such as these do not focus on the complex issues required to make technology integration in surgical

environments a reality. The focus of our future research will be in expressing the complex requirements that need to be satisfied in this domain, and determining how well existing OTS architectures address these requirements. The result, we hope, will be a component-based architecture where new software technologies may be rapidly introduced into the surgical suite.

Acknowledgements

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10.3 Posters

Copies of the eight posters produced during this reporting period are reproduced in this section.

10.3.1 Alaoui 2000b: Implementing a firewall ...

Poster is reproduced on the next page. Presented at the CARS conference June-July 2000 in San Francisco, CA.

Implementing a Firewall for Improved Patient Data Security

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Introduction

The confidentiality of medical information, including patient data security, is an increasingly important issue in today's health care environment. The Health Insurance Portability and Accountability Act (HIPAA) of 1996 requires the Department of Health and Human Services to create specific rules for managing the security and privacy of computer-based patient medical records. Although Congress recently failed to pass medical privacy legislation, health care organizations, including medical researchers, nonetheless will need to be more concerned about protecting the confidentiality of electronic medical records.

In this poster, we present our experience in implementing a firewall for improved patient data security. The poster gives some background on the procurement process, outlines our network architecture, and presents a sample clinical application.

Network Architecture

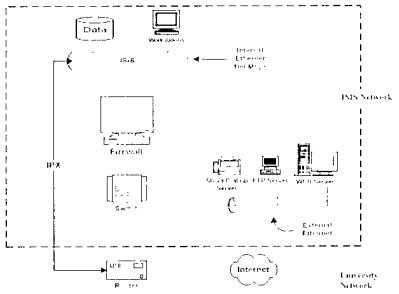

Figure 1: Network Architecture

With the installation of the firewall, the ISIS network was partioned into two segments: an internal Ethernet (trusted network) and an external Ethernet (untrusted network) as shown in Figure 1. This partioning is based on a Cisco Catalyst 5509 switch, which provides 100 Mbps Ethernet connectivity.

All ISIS staff members are connected to the internal Ethernet, which resides behind the Gauntlet Firewall. Patient identifiable data, email servers, and data not meant to be public is stored within the internal Ethernet. The webservers, FTP servers, and Shiva dial up server were placed on the external Ethernet.

The firewall is installed on a Micron PC with 128 MB RAM and a 10-gigabyte hard drive. The PC has 2 network cards, one for the internal network and one for the external network. The firewall version is Gauntlet 4.2 and the operating system is Unix BSD 3.1 (Berkeley University).

Access to the internal ISIS network is only possible through the firewall, except for IPX protocol (Novell Netware) which is routed around the firewall. To access the internal network via FTP or Telnet registered users are authenticated and prompted to enter a password.

Significance

The Imaging Science and Information Systems (ISIS) Center, Department of Radiology, Georgetown University Medical Center, is an important civilian research laboratory for the Department of Defense (DOD). The ISIS Center has established a reputation for technical sophistication and organizational effectiveness in medical technology research through projects such as the DIN-PACS (Digital Imaging Network – Picture Archiving and Communications), the deployable radiology network (Project DEPRAD in support of NATO troops in Bosnia), and digital mammography. The ISIS Center also successfully competes for extramural funding from other government agencies including the National Library of Medicine, National Institutes of Health, and the National Science Foundation in the areas of image processing, computer-aided diagnosis, telemedicine, and image-guided therapy.

The ISIS Center has undergone major changes in its research environment, particularly with regards to the storage and manipulation of patient data. Many projects are beginning to acquire, manipulate and archive patient identifiable information on the ISIS Center local area network. This includes running clinical trials for government and commercial funding agencies subject to Food and Drug Administration rules and regulations. In addition, investigators, physicians, and patients increasingly require remote access to such data using dial-up and web-based technology. Whereas the ISIS Center has historically not faced major data security problems in its links with untrusted networks, these two new conditions required developing a plan for managing the security and confidentiality of patient identifiable information on its LAN.

In 1998, the ISIS Center embarked on a program to improve security measures for protecting medical information. As part of that effort, the ISIS Center issued a Request for Proposal (RFP) for firewall and secure remote access technology Based on the responses to that RFP, a Gauntlet firewall was selected and installed.

Firewall Configuration

The Gauntlet firewall is a hybrid firewall. This means it operates as an application gateway and as a circuit gateway. Table 1 illustrates some of the application proxies available that are important to the ISIS Center.

Proxy	Authentication	Extras
HTTP	Yes	Active X, Java, URL Filtering, Cyber Patrol
SSL	No	
SMTP	Yes	Virus Scan, limit size, Anti-Relay, Anti-Spam
POP3	Yes	
FTP	Yes	Transparent, Command Filtering
SQL	No	
Netmeeting	No	
Plug Proxy	No	Can be configurable to any port

Table 1: Application Proxies

One of the limitations of all available firewalls is that the DICOM (digital imaging and communications in medicine) standard or IPX proxies are not available. Therefore, a work around was created so that DICOM images could be transferred. In all cases, packet screening filters were created, allowing communications between defined internal and external computers. In some cases, a plug proxy was configured to allow the transmission of DICOM images through the firewall. To access Novell networks at the hospital using IPX Protocol, the only solution was to route Novell traffic around the firewall.

The other security measure of importance to ISIS is the ability to create virtual private networks (VPN) that enable secure Internet use between remote users, branch offices, and research partners by encrypting the traffic.

For managing the firewall, we use the Gauntlet firewall manager as the primary tool. It is a secure graphical interface accessible from authorized computers on the trusted network and it allows remote workstations access to the firewall configuration.

As the firewall administrator needs to be constantly aware of any attempted attacks, the reporting capabilities of Gauntlet are very useful in this regard. The firewall administrators can configure and customize reports and alerts as to:

- Frequency of reports
- Configure type of alerts
- Message log
- Receive alerts and reports by email

Using the reporting module of Gauntlet the following can be logged and monitored: all failed processes, failed access attempts, packets that failed to pass the filter and activities contrary to firewall configuration. Figure 2 is a screen capture showing a message that is set to notify the administrator about all alerts and possible items of interest.

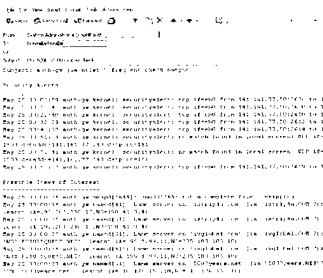

Figure 2: Alert Message

Steps Toward Security

Risk and needs assessment were undertaken to identify the potential risks in the network and weigh them against the threats of attack, loss of data, etc. Questionnaires were circulated to all researchers to determine the systems and communications/network protocols used within the ISIS Center and at remote sites that collaborate with the ISIS Center

All this information was used to create a comprehensive request for proposal (RFP). Vendors were asked to respond to specific user questions as well as being told what the expectations were for the vendor and/or firewall product.

RFP responses were evaluated independently by several ISIS members. SecureMethods, Inc. (formerly Dyncorp), was selected to install a Gauntlet firewall. SecureMethods technical experts met with ISIS Center network personnel to discuss the new data security policies and procedures that would affect the work of independent investigators and staff. It was important to keep all staff members informed as the firewall installation could potentially impact their use of network services. Finally, installation and implementation was scheduled over a weekend. During this time, access to the Internet and the outside world was limited.

Multiple system tests were performed to validate the configuration and the operations of the firewall. Changes were made when user expectations were not met or when important tasks could not be carried out because of the firewall settings. Each project was analyzed and tested to ensure that a mechanism was found to allow the project to continue to operate with the firewall in place. The maintenance of the firewall and modification to the configuration are ongoing tasks.

Clinical Applications

Figure 3:
Mobile CT Gantry and Table

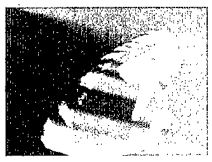

Figure 4:
3D Visualization

As mentioned in Section 3, the ISIS Center often has a need to exchange DICOM images with clinical departments at the hospital or other research groups. One example of this need is related to our work with the Interventional Radiology group. We are providing engineering support and systems integration assistance for a mobile CT scanner (Figure 3) The scanner is used during interventional cases to obtain a series of axial images, which can then be reconstructed into a three-dimensional display for visualization purposes (Figure 4). Since the engineers working on this project are situated at our research group, we need to transfer the CT images from the hospital to the trusted network of ISIS Center. This image transfer is done using the DICOM protocol, and requires appropriately configuring the firewall as discussed in the previous section.

Conclusion

A Gauntlet firewall was installed to provide improved security for the research environment at the ISIS Center. This required some changes to the network architecture and operating environment. Some disruption was experienced during the installation, but the transition to a secure environment went relatively well. Participation by all group members was critical towards minimizing any inconveniencies. The ISIS Center is well positioned for future initiatives where a secure environment is required.

ACKNOWLEDGEMENTS

This work was supported by the U.S. Army under grants DAMD17-96-2-6004 and DAMD17-99-1-9022 and the National Library of Medicine under grant NO1-LM-6-3544 The content of this poster does not necessarily reflect the position or policy of the U.S. Government

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10.3.2 Cleary 2000d: Image-guided minimally ...

Poster is reproduced on the next page. Presented at the ATA 2000 conference in Phoenix, Arizona.

Image-Guided, Minimally Invasive Spine Procedures
Intraoperative CT, 3-D Visualization and Robotics

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Introduction

Minimally invasive procedures can spare the patient the trauma associated with open surgery, and result in significant cost savings. Advances in image-guided techniques are driving the development of minimally invasive procedures. At Georgetown University Medical Center, we are developing a program to advance the state of the art in image-guided, minimally invasive spine procedures. This is a collaboration between an engineering-based research group (ISIS Center) and physicians from the radiology and neurosurgery departments. The thrust of this effort is to introduce technology developments such as intraoperative CT, three-dimensional (3-D) visualization, and robotic guidance into the clinical area. This poster will highlight some of the initial results and upcoming developments.

Intraoperative CT

The Tomoscan M mobile CT scanner (Philips Medical Systems, Eindhoven, Netherlands) is easily transportable within the hospital and consists of three components: a gantry, a CT table, and an operator's workstation (**Figures 1 and 2**). The aperture of the gantry diameter is 60 cm with a maximal field of view of 46 cm. Both the gantry and CT table can translate, 35 cm and 150 cm respectively.

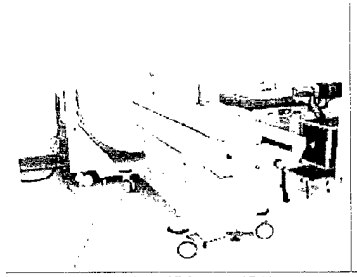

Figure 1: Mobile CT Gantry and Table

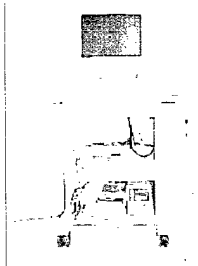

Figure 2: Operator's Workstation

The mobile CT became operational at Georgetown in April of 1998, and has been used in about 120 procedures as of February 2000. This includes 77 neuroradiological procedures in the interventional suite (vertebroplasty, discograms, radiofrequency and laser ablations, facet blocks, bone biopsies), 30 procedures in the operating room (head, neck, and spinal tumor resections), some vascular interventional procedures (drainage placements and biopsies), and radiation treatment planning cases.

Vertebroplasty: Interventional Suite

Percutaneous vertebroplasty is a minimally invasive technique where polymethylmethacrylate (PMMA) bone cement is injected directly into a vertebral body under fluoroscopic and/or CT guidance. The procedure is done in the interventional suite (**Figure 3**). The procedure is done under bi-plane fluoroscopy (Siemens Neurostar TOP). The injection of PMMA (bone cement) is shown in **Figure 4**. The mobile CT scanner (**Figure 5**) is used as-needed for several purposes: 1) prior to vertebroplasty to define defects in cortical bone and needle placement; 2) during the procedure to evaluate indeterminant PMMA extravasation and to check needle placement; and 3) post-procedure to verify the amount of filling within the vertebral body. The equipment placement and room layout is shown in **Figure 6**.

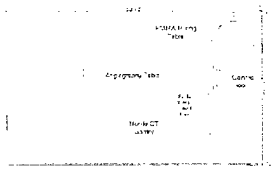

Figure 6: Interventional Suite Equipment Layout

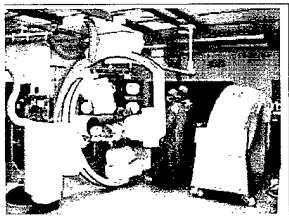

Figure 3: Interventional Suite

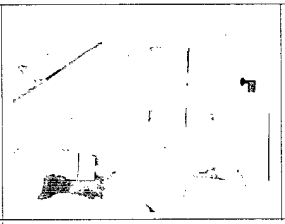

Figure 4: Injection of PMMA

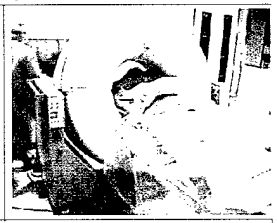

Figure 5: CT Scan Preparation

ACKNOWLEDGEMENTS: This work was supported by the U.S. Army under grants DAMD17-96-2-6004 and DAMD17-99-1-9022. The content of this poster does not necessarily reflect the position or policy of the U.S. Government.

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Tumor Resection: Operating Room

For complex spine tumor cases, the mobile CT is moved to the operating room. The patient is placed on the CT table. Sterile plastic drapes are applied to the opening of the gantry aperture. An initial scanogram is taken to locate the desired vertebral level of the spine. During the procedure, the gantry can be moved away from the table to allow complete access to the patient. The gantry is re-docked for scanning as needed for intraoperative visualization. The preparation and CT scanning time averages 15 - 20 minutes per series. The Radiation Safety Office determined that personnel must either wear lead protection or remain at least 12 feet from the center of the gantry during scanning. The operator's workstation is placed outside a 12-foot perimeter. The CT scanner in the operating room is shown in **Figure 7**. A diagram of the operating room layout is shown in **Figure 8**.

Figure 7: Mobile CT in the Operating Room

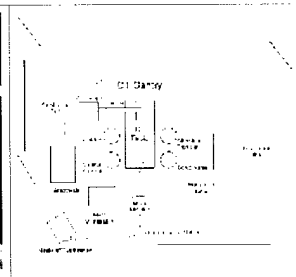

Figure 8: Operating Room Layout

In 6 of the 17 spinal neurosurgical cases to date at Georgetown, the CT provided information that altered the course of the surgery, including: 2 cases of more complete tumor resections, 3 cases of more complete ventral decompression of the brainstem, and one case of a correction of a slipped/rotated transverse process hook. There were no clinically detectable complications from the added use of CT.

Operating Room Case Study: Tumor Resection

A 42-year-old woman with severe, deforming rheumatoid presented with spastic quadriparesis and numbness. Pre-op MR images of the cranio-cervical junction revealed basilar invagination with brainstem compression. The patient underwent a transoral odontoidectomy (**Figures 9, 10, and 11**).

Figure 9: Intraoperative Scanogram The initial scanogram showing occipito-cervical stabilization and C3-4 anterior spine plate from prior surgery, placement of instrumentation for transoral exposure, and patient placement in halo vest.

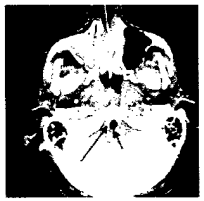

Figure 10: Initial Intraoperative CT After initial resection, intraoperative axial CT scan revealed continued compression of the brainstem by a fractured portion of the odontoid (long arrow) obscured from direct visualization by pannus and resection cavity (short arrow).

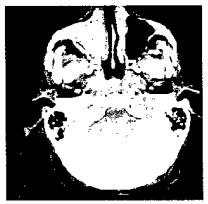

Figure 11: Final Intraoperative CT After further resection, intraoperative CT scan verified complete odontoid resection. Post-operatively, the patient had return of strength and resolution of her brainstem symptoms.

3-D Visualization

As part of the research program, a software package for image visualization has been created with the following capabilities:

- DICOM receiver to accept images from mobile CT, fluoroscopy, and digital subtraction angiography (DSA) units
- 2-D viewing capability (single slices or multiple slices up to 8 by 8)
- Segmentation function based on histogram thresholding
- 3-D visualization
- Registration of DSA images by manual pixel shifting

The software runs under Windows NT on a desktop PC. The user interface is shown in Figure 12. The imaging and visualization software library Analyze, from Mayo Clinic, is used to provide much of the base functionality. This package was purchased off-the-shelf to jump-start the development process.

As a feasibility study, a 3-D visualization module has been created that can be used to examine the spread of bone cement after vertebroplasty procedures. The mobile CT scanner is used to acquire a set of images. These images can then be sent to the visualization software via a DICOM network interface where the bone cement and vertebral body are segmented based on histogram windowing (**Figure 13**). The resulting images can be rendered in 3-D for viewing by the physician (**Figures 14 and 15**).

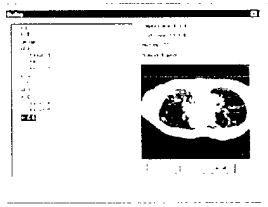

Figure 12: User Interface

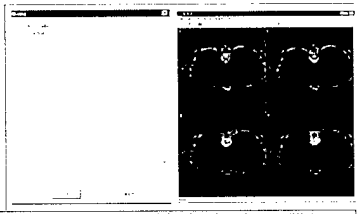

Figure 13: Thresholding of Vertebroplasty Images (Histogram on left, resulting images on right)

Figure 14: 3-D Visualization (Vertebral body, bone cement in green)

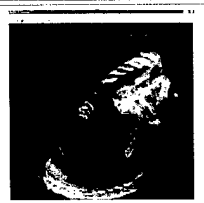

Figure 15: 3-D Visualization (Entire torso view)

Robotics

Recently, we have begun developing robotics for spinal procedures as part of a collaboration between Georgetown, the Urology Robotics Laboratory (URobotics Lab) of the Johns Hopkins Medical Institutions (http://urology.jhu.edu/research/urobotics), and the Computer Integrated Surgical Systems and Technology Center (http://cisstweb.cs.jhu.edu/web/) centered at the Johns Hopkins University (an NSF-funded Engineering Research Center). The aim is to assist the neuro-interventionalist in placing and advancing needles and associated instruments in and around the spine by using a mechanical needle holder and driver (**Figures 16 and 17**). The long-term goal is to develop a robotic system that can work cooperatively with the physician to improve instrument placement accuracy in spinal procedures.

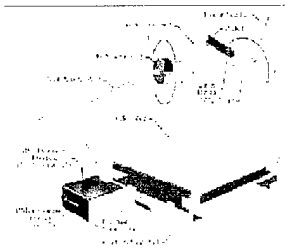

Figure 16: "Needle Driver" RCM-PAKY Robot

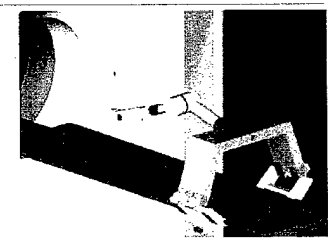

Figure 17: Mounting on Table and CT Gantry

10.3.3 Cleary 2000e: CT-directed robot ...

Poster is reproduced on the next page. Presented as part of a demonstration at the MICCAI 2000 conference in October 2000 in Pittsburgh, PA.

CT-Directed Robotic Biopsy Testbed
System Concept

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INTRODUCTION

Biopsy is a common procedure in the medical field. While in most cases this procedure can be completed without difficulty, there are limitations to the accuracy obtainable using freehand techniques. In addition, CT-directed biopsy can be tedious and time consuming, since frequent re-imaging may be required. For these reasons, we are developing a robot biopsy testbed incorporating a mobile CT scanner, a small "needle driver" robot, and an optical localizer. A system diagram is shown in Figure 1.

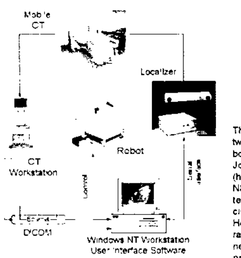

Figure 1: Testbed components.

The goals of the testbed are to:

1. Develop a demonstration system for robotically assisted biopsy
2. Compare robotically assisted biopsy to the current manual technique
3. Serve as a testbed for investigating software architecture for incorporating multiple medical devices

This testbed is part of a collaboration between Georgetown and the Urology Robotics Laboratory (URobotics Lab) of the Johns Hopkins Medical Institutions (http://urology.jhu.edu/urobotics/) and the NSF Computer Integrated Surgical Systems and Technology Center (http://cisstweb.cs.jhu.edu/web/) at the Johns Hopkins University. As part of this collaboration, we are also planning to apply the needle driver robot to percutaneous spine procedures such as nerve and facet blocks [1].

MANUAL BIOPSY TASK

Manual biopsy procedure requires a computed tomography (CT) scanner, a trained technologist, a special biopsy needle, and a "biopsy tray" with appropriate syringes, needles, anesthetic solution, and sterile towels [2,3]. Each patient receives a pre-procedure CT scan to ascertain the lesion site and to plan the route of approach for the biopsy. A number of planning CT slices are obtained to calculate the desired distance from skin to target. The chosen trajectory should avoid major organs if possible. The entry site is then prepared in a sterile fashion and a local anesthetic is applied. At this point, a biopsy needle is inserted partially along the biopsy track, and CT images are taken to reconfirm proper site and trajectory. If unsatisfactory, multiple needle repositionings are performed and serial CT slices are obtained until the needle is in the target. A final CT image is obtained to confirm that the needle tip is in the target tissue before any core biopsy samples are taken. While one tissue core may suffice, many operators take two or three samples. Some may choose to have a surgical pathologist or cytologist present to examine the tissue specimen for suitability. Once the biopsy is completed, some operators may obtain one last CT series following needle removal to demonstrate the biopsy defect in the target tissue.

GUIDED BIOPSY SYSTEMS REVIEW

Other researchers have developed robotic systems to aid in biopsy tasks. These include passive positioning systems, which provide image guidance to assist the physician in orienting the biopsy, as well as semiautonomous robots which position, drive and guide the biopsy needle under remote physician control. The PinPoint™ system, developed by Marconi Medical Systems (Cleveland, OH, formerly Picker), is representative of the passive robotic biopsy assistant type [4]. PinPoint is a frameless stereotactic arm for use in planning CT-Guided biopsy (Figure 2-a). The arm is direction encoded so that the intervention path can be visualized on CT and evaluated. Once the optimum biopsy needle path is determined, the Pin Point arm can be locked into place to serve as a stationary guide to needle placement (Figure 2-b). Semiautonomous systems have been developed for use in breast and brain tissue biopsy. The Mammotome®, manufactured by Ethicon Endo Inc (Cincinnati, OH) a Johnson and Johnson Company, and the Advanced Breast Biopsy Instrumentation (ABBI®) system, a product of the United States Surgical Corporation (Norwalk, CT), are two widely available breast biopsy systems. Both systems allow remote, image-guided placement and manipulation of the biopsy tool. The Mammotome breast biopsy system is composed of a thin probe attached to a motorized unit and an integrated vacuum source [5]. Under local anesthesia, the biopsy probe is introduced through a ¼ inch incision. The probe is navigated under image guidance to the target selected by the physician. Both CT and ultrasound guidance are compatible with the Mammotome. Once in position, a vacuum system draws tissue into the probe core and harvests small samples. The operator can navigate the probe to more than one target per insertion, allowing wide sampling from only one access point [6]. The ABBI system, allows stereotactically guided, mechanically driven fine needle biopsy and a novel "core needle" breast biopsy [7]. Rather than harvesting microhistological specimens from a variety of locations in the breast, the "core needle" breast biopsy option removes a single, solid specimen, which can vary in size from 5 mm to 20 mm, depending on physician preference. There is some evidence that one-piece cytologic specimens can aid in the diagnosis of certain breast disorders, an advantage of the ABBI core needle biopsy. Studies comparing the effectiveness of the ABBI core needle biopsy to the Mammotome's microhistological approach are ongoing [8].

Because the ABBI core needle system has the potential to remove large pieces of target tissue under physician guidance, it has potential as a treatment modality in addition to a biopsy tool. This application is still under investigation. Two representative semiautonomous neurosurgical biopsy systems include the Minerva, developed by the Laboratory of Microengineering at the Swiss Federal Institute of Technology in Lausanne, Switzerland, and the NeuroMate™, manufactured by Integrated Surgical Systems (Davis, CA). Minerva is a CT guided, multifunction neurosurgical robot [9]. It operates inside a CT gantry with free longitudinal movement allowing cranial scans at any level. Under the physician's remote control, the Minerva robot can manipulate two stereotactic instruments in addition to the tool for automatic penetration of the skin, skull, and meninges. This allows the Minerva to perform a complete stereotactic procedure without physical intervention by the physician. In addition to biopsy, this system has been used for deposition of living encapsulated cells, electrode implantation, placement of radioactive sources, electrostimulation, and tissue aspiration [10]. The NeuroMate stereotactic surgical system was originally developed at the University of Grenoble, France [11, 12] and is now available from ISS. NeuroMate is an image-directed robotic assistant for frameless stereotactic neurosurgical applications (Figure 3). It can function to orient and position surgical instruments under image guidance. Much like Minerva, it is also capable of carrying out surgical procedures under remote physician control.

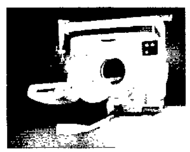

Figure 2-a: PinPoint™ arm (upper left) and CT/Fluoroscopy system

Figure 2-b: PinPoint™ arm locked in place to serve as a needle guide

(Courtesy of Marconi Medical Systems: http://www.picker.com/ct/ctro/ctrovenue.html)

Figure 3: NeuroMate™ robotic assistant for neurosurgical stereotactic applications

(Courtesy of Integrated Surgical Systems: http://www.robodoc.com/neuromat.htm)

MOBILE CT SCANNER

The Tomoscan M is a mobile CT scanner (Philips Medical Systems, Eindhoven, Netherlands) that is easily transportable within the hospital. The system has three components including a gantry, CT table, and operator's workstation. The gantry aperture is 60 cm with a maximal field of view of 460 mm. Both the gantry and the CT table can translate, 35 cm and 150 cm respectively. The images have a resolution of 512 by 512 pixels and can be transferred to other systems using the digital imaging and communications in medicine (DICOM) standard. Protocols for cervical, thoracic, and lumbar spine exist with slice thickness options of 2, 3, 5, and 10 mm. The system has a tube voltage of 130 kV and uses a relatively low tube current between 10 and 50 mA, thereby minimizing dose exposure.

THE ROBOTIC SYSTEM

The robotic system will be based on the PAKY-RCM (Percutaneous Access to the KidneY - Remote Center of Motion) robot that has been initially developed at Johns Hopkins for percutaneous access of the renal collecting system [13, 14]. The robot, schematically represented in Figure 4, consists of a passive positioning and supporting arm (The GREY Arm) [15], an active remote center of motion orientation mechanism (RCM), and a radiolucent needle driver (PAKY). The device will be mounted over the CT table using a bridge fixture as depicted in Figure 4. The overall system comprises eleven degrees of freedom (DOF). The first eight DOF are used for the initial positioning of the robot in close proximity of the skin insertion site and firmly locked during the operation. The remaining three DOF, implemented by the RCM robot and PAKY needle driver, are sufficient for orienting and inserting the needle at the desired target through the preset skin insertion point. The main advantage of this minimal kinematic architecture is the inherent safety given by the restricted mobility of the mechanical components. Moreover, separating the kinematics of the orientation and needle insertion yields decoupled needle motion capabilities, thus improving safety. The needle driver is constructed of acrylic plastic which is radiolucent and easy to manufacture as a sterile disposable part. Driver radiolucency is essential in image-guided procedures for providing unimpeded target visualization. Whereas the driver is sterilized, in clinical use the additional components of the system in close proximity of the operation site are covered with a sterile bag. The robot accommodates joystick control for simple maneuvers and full computer control for the actual image-guided procedure. The electronic circuitry will be fully enclosed in the supporting bridge of the arm, so that the robot is self-contained and only requires a DC power supply. The complete system is presently under development. The new design incorporates a major improvement over the first generations of the RCM robot, the "Ball-Worm Transmission" recently developed at the Hopkins URobotics Lab. This transmission fulfills the need for implementing a simple and small no-backlash (no play between the input and output shafts) rotational transmission for miniature surgical robotics. With this addition the RCM exhibits superior motion tracking and positioning capabilities. Detailed design and performance characteristics will be presented in the near future.

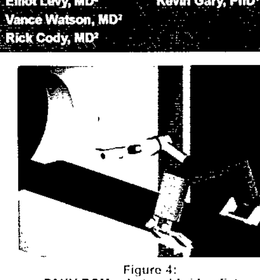

Figure 4:
PAKY-RCM robot and bridge fixture

LOCALIZER

The optical localizing system (Hybrid Polaris, Northern Digital, Waterloo, Canada) is used to determine the orientation and position of tracked objects relative to the camera system. Objects are tracked by rigidly attaching retro-reflective spheres or active infrared LED's (IREDs). The spheres or IREDs can be detected by the camera system and used to determine the location and orientation of the object. This version of the Polaris can track up to 3 active and 3 passive tools simultaneously and is controlled via the serial port of the host computer. By applying reflective spheres directly to the table, we are able to track the CT table and gantry. Similarly, tracking spheres located on the robot and end-effector will enable us to directly monitor the robot position. This is especially important as a safety feature in order to verify the robot's own encoders. Finally, a dynamic reference base (DRB) tracker applied to the patient will enable us to dynamically reference the patient compensating for patient movement or providing a warning when motion occurs. The optimum use for the localizer is still under discussion, but additional uses include robot calibration upon start-up, and assistance in marking the biopsy entry point.

BIOPSY SCENARIO

The scenario envisioned for robotic spine biopsy is as follows.

1. The patient is positioned on the table and a series of axial scans are obtained
2. The scans are transferred from the operator's workstation to the CT workstation over an Ethernet connection using the DICOM protocol
3. The user interface software allows the physician to select the axial scan of interest and the region to be biopsied (entry location and target point)
4. The entry location for the biopsy is marked on the patient's skin (using the laser lights on the scanner and measuring off the centerline as necessary)
5. The robot is manually positioned at the skin entry point
6. The robot automatically orients the needle and inserts it
7. A CT scan is obtained to verify the needle position
8. The biopsy sample is taken

The testbed will be verified on phantoms and cadavers before any clinical trials are planned. The initial goal is to evaluate the accuracy obtainable using robotically assisted biopsy as compared to the current manual technique as described in Section 2. The interventional phantom shown in Figure 5 will be used in these initial studies.

Figure 5: Interventional phantom

(Courtesy of CIRS, Inc.: http://www.cirsinc.com)

SYSTEM SOFTWARE DESIGN

Current software systems deployed in surgical environments do not lend themselves to open software architectures that utilize off-the-shelf (OTS) components. These systems are developed from a single functional perspective; even if multiple functional capabilities are integrated, they are tightly integrated in a closed fashion that results in large, costly, monolithic systems. It then becomes difficult to integrate these systems with systems dedicated to other functional areas. An example of this is the need to offload images from the CT workstation to the NT workstation in our testbed environment (see Figure 1). A more desirable approach is to view technology integration via open software architectures, where various hardware and software components may be integrated on top of a common software "bus". Our approach to integrating the hardware and software components of the robotic biopsy testbed is to develop functional component wrappers for each component and integrate them on top of an open architecture. The "wrappers" will shield implementation details from other components, reducing "hardcoded" dependencies between components and enabling the dynamic composition of functionality to meet application requirements.

At the same time, the architecture must support drill-down optimizations, fault tolerance, and error handling, to ensure the complex requirements of the application domain are met. To provide a clearer picture of how these components may interact to support the robotic biopsy application, we describe component collaborations using the Unified Modeling Language (UML) collaboration diagram shown in Figure 6. This figure shows the collaboration between high-level software components, hardware components, and the physician. Although UML collaboration diagrams are typically reserved for software components, we find this a useful notation for expressing workflows between hardware and software components, as well as indicating the role of operator intervention. Steps are numbered according to the sequence in which they are performed. This diagram shows that the CT workstation first acquires a study of images from the Mobile CT. The scans are then sent to the NT workstation, and path planning is done to determine the slice and planned path to the lesion. The NT workstation tells the Optical Localizer to track objects in the application space, which is done continuously for the rest of the procedure. The Mobile CT and PAKY-RCM robot are then positioned manually by the physician. The NT workstation then orients the needle by transmitting path and coordinate information to the robot, and the needle is driven to the target. A verification scan is then taken. The figure shows at a high level the interactions that must take place between components. Each interaction will in fact be realized at a lower level as a number of messages sent between objects in the environment. In order to facilitate the interactions between components, the architecture must provide some common services to tie the components together. Such services include DICOM communication (CT and NT workstations), task synchronization, asynchronous and synchronous communication, error handling and event notification, logging, coordinate transformations, and redundant verification (between the localizer, mobile CT, and robotic device). An important, domain-specific example is the mapping of coordinate systems between the optical tracker, NT user interface software, and the robot. This integration task requires a precise mapping of the relative coordinate systems of each component in order to carry out visualization and verification tasks in the application space. The current architecture is being developed in C++ using DICOM as the image transfer protocol and communication with hardware components via wrapper libraries that talk with specific interfaces (such as serial ports or special-purpose device cards). All component wrappers are being developed with well-defined object interfaces. We view this as a first step towards a more general, open software architecture where hardware and software components are integrated and configured dynamically to meet the requirements of families of surgical applications [16]. We are currently evaluating state-of-the-art middleware technologies such as CORBA, DCOM, and Jini for this purpose. We also plan to work with our Johns Hopkins collaborators to port the Modular Robot Control (MRC) library to the testbed.

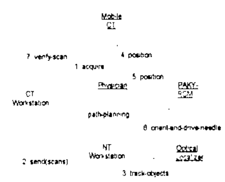

Figure 6: Testbed software component collaboration diagram

CONCLUSION

This poster describes an ongoing project in developing a robotic biopsy testbed. Once the system is integrated, it will be used to compare robotically assisted biopsy to the current manual technique. This will require the continued close cooperation between the engineers and physicians and the development of appropriate measures to judge the success of the procedure.

ACKNOWLEDGMENTS

This work was supported by the U.S. Army under grant DAMD17-99-1-9022. The content of this poster does not necessarily reflect the position or policy of the U.S. Government.

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10.3.4 Cleary 2000f: Image-guided robotic delivery ...

Poster is reproduced on the next page. Presented at the NIH Tumor Targeted Delivery Systems Conference in September 2000.

Image-Guided Robotic Delivery System for Precise Placement of Therapeutic Agents

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Matthew Freedman, MD
Mark Clifford, MS
David Lindisch, RT
Sumiyo Onda, BS
Lei Jiang, BS

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INTRODUCTION

The effectiveness of conventional solid tumor treatment is limited by the systemic toxicity and lack of specificity of chemotherapeutic agents. Present treatment modalities are frequently insufficient to eliminate competent cancer cells without exceeding the limits of toxicity to normal tissue. The coming generation of cancer therapeutics depends on the precise targeting and sustained release of antitumor agents to overcome these limitations. We are developing an image-guided, robotic system that could be applied to precise intratumoral placement of anticancer drugs and sustained release devices to advance this new treatment paradigm.

ROBOTIC BIOPSY TESTBED

The long-term goal of our research program is to develop an integrated system to enable the next generation of percutaneous procedures. As a first step in this effort, we are assembling a robotic biopsy testbed to serve as a platform for development and integration. The technical developments that comprise the testbed include: 1) a mobile CT scanner; 2) 3D image visualization, 3) localization (position tracking); 4) a small "needle driver" robot; and 5) software integration of the system components. In addition to providing a framework for development, the testbed will be used to compare robotically assisted biopsy to the current manual technique. A system diagram is shown in Figure 1. In this poster, we will briefly describe each of these developments.

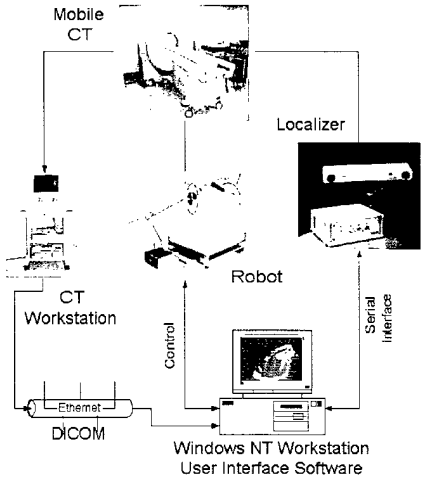

Figure 1: Robotically assisted biopsy testbed

MOBILE CT SCANNER

As an initial step in our research program, we have integrated a mobile CT scanner (Philips Tomoscan M) into the hospital operations to provide intraoperative images [Hum et al. 2000]. At Georgetown, the mobile CT scanner has been used in interventional radiology, the operating room, radiation medicine, the neurosurgery intensive care unit, and the pediatrics ICU. The major procedures impacted by the availability of intraoperative CT are in interventional radiology and in neurosurgery. Since May of 1998, the mobile CT has been used in over 125 procedures at our institution. Since both the gantry and the table can move during scanning, the gantry can be used with the CT table (as done in the operating room: Figure 2a) or with another table such as a fluoroscopy table (as done in the interventional suite: Figure 2b).

Figure 2a: Mobile CT in operating room during craniotomy

Figure 2b: Preparing to scan in interventional suite

3D IMAGE VISUALIZATION

To demonstrate the potential of 3D image reconstruction, 3D visualization software was developed to examine the spread of bone cement after vertebroplasty procedures [Watson, Cleary and Lindisch 1999]. The images were acquired by the mobile CT scanner in the interventional suite. Off-line, these images were then transferred to a Windows NT personal computer using the digital image communications in medicine (DICOM) standard (Figure 3a). The visualization software was then used to segment the bone cement and vertebral body based on histogram windowing. The resulting images can then be rendered in 3D for viewing by the interventional radiologist (Figure 3b). To date, only a feasibility study has been completed, but the interventional radiologist has stated that the images are useful for visualizing the spread of bone cement.

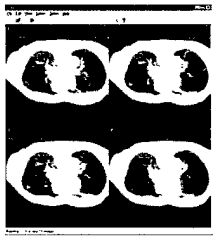

Figure 3a: Thoracic CT scans

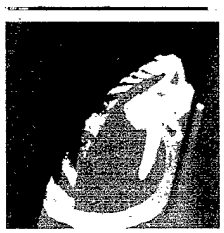

Figure 3b: 3D visualization

LOCALIZATION (POSITION TRACKING)

The optical localizing system (Hybrid Polaris, Northern Digital, Waterloo, Canada) is used to determine the orientation and position of tracked objects relative to the camera system. Objects are tracked by rigidly attaching retroreflective spheres or active infrared LED's (IREDs). The spheres or IREDs can be detected by the camera system and used to determine the location and orientation of the object. This version of the Polaris can track up to 3 active and 3 passive tools simultaneously and is controlled via the serial port of the host computer. In the biopsy testbed described here, we use an interventional phantom with a passive tracker rigidly attached to the spinous process (Figures 4a, 4b).

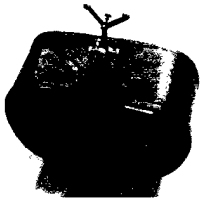

Figure 4a: Interventional phantom with passive tracker rigidly attached to spinous process

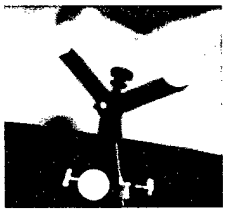

Figure 4b: Passive tracker and reflective spheres

"NEEDLE DRIVER" ROBOT

The robotic system is based on the PAKY-RCM (Percutaneous Access to the KidneY - Remote Center of Motion) robot developed at Johns Hopkins for percutaneous access of the renal collecting system [Cadeddu et al. 1998, Stoianovici et al. 1998]. The robot, schematically represented in Figure 5a, consists of a passive positioning and supporting arm (The GREY Arm), an active remote center of motion orientation mechanism (RCM), and a radiolucent needle driver (PAKY). The device will be mounted over the CT table using a bridge fixture as depicted in Figure 5b.

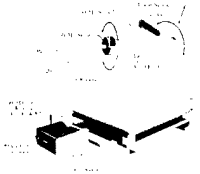

Figure 5a: Needle driver robot

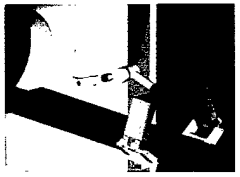

Figure 5b: PAKY-RCM robot and bridge fixture

SOFTWARE INTEGRATION

Current software systems deployed in surgical environments do not lend themselves to open software architectures that utilize off-the-shelf (OTS) components. These systems are developed from a single functional perspective, it is difficult to integrate these systems with systems dedicated to other functional areas. Our approach to integrating the hardware and software components of the robotic biopsy testbed is to develop functional component wrappers for each component and integrate them on top of an open architecture. The "wrappers" will shield implementation details from other components, reducing "hardcoded" dependencies between components and enabling the dynamic composition of functionality to meet application requirements. To provide a picture of how these components may interact to support the robotic biopsy application, we describe component collaborations using the Unified Modeling Language (UML) collaboration diagram shown in Figure 6.

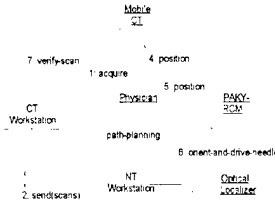

Figure 6: Testbed software component collaboration diagram

CONCLUSION

A robotic system for precise placement of needles and related instruments has been described. The system is general purpose and may be applied to many clinical scenarios. Potential advantages of the robotic delivery system are:

1. To achieve a high enough concentration, such a system may be used to precisely place chemotherapeutic agents into the site of interest.
2. Precise placement may allow a higher local concentration of these agents
3. The system may also be used to deliver other forms of therapy including cryotherapy, thermotherapy, engineered cells, or gene transfer.
4. The system may be used to combine biopsy with treatment.

ACKNOWLEDGMENTS

The robotic system was developed by Dan Stoianovici, PhD, and colleagues at the Urology Robotics Laboratory http://urology.jhu.edu/ at Johns Hopkins Medical Institutions. The biopsy testbed software is being developed in collaboration with Russell Taylor, PhD, and colleagues at the Computer Integrated Surgical Systems & Technology Engineering Research Center (CISST ERC) http://cisstweb.cs.jhu.edu at Johns Hopkins University.

This work was supported by the U.S. Army under grant DAMD17-99-1-9022. The content of this poster does not necessarily reflect the position or policy of the U.S. Government.

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10.3.5 Henderson 2000: Mobile CT for ...

Poster is reproduced on the next page. Presented at the Congress of Neurological Surgeons conference September 2001 in San Antonio, TX.

Mobile CT for Intraoperative Imaging in Neurosurgery: Spinal and Intracranial

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INTRODUCTION

Purpose: A mobile computed tomography (CT) scanner has been used in the operating room for intracranial and spinal procedures to improve intraoperative visualization, to provide updated imaging information for navigation, and to verify surgical correction.

Methods: The Tomoscan M CT consists of a translatable gantry, a translatable table, and an operator's workstation. The patient is placed on the CT table, and prepped in the usual fashion. The aperture of the gantry is covered with sterile plastic drapes. The gantry is docked to the table for intraoperative CT scanning as needed for navigation and verification during surgery. Each series of scans requires approximately 15-20 minutes.

Results: We report on 17 spinal procedures and 4 pediatric tumor resections. In the spine, the use of intraoperative CT changed the course of the surgery in 6 out the 17 cases. CT was beneficial in confirming adequate ventral clival and craniocervical decompressions, assisting in more complete tumor resections, and verifying correct instrument placement. For the intracranial tumor resections CT helped define tumor margins intraoperatively, and assisted in navigation around critical anatomy. Problems include limitations of positioning, inability to alter table position (except height), lack of table adaptations and the width of the CT table.

Conclusion: In selected craniocervical, spine tumor and intracranial procedures, the mobile CT provides immediate feedback on complex anatomy and verification that surgical goals have been met. Through its compatibility with emerging technology - MRI, ultrasound, radiosurgery – the mobile CT offers a broad repertoire of potential applications.

METHODS

The Tomoscan M mobile CT scanner is easily transportable within the hospital and consists of three components: a gantry, a CT table, and an operator's workstation (**Figures 1 and 2**). The aperture of the gantry diameter is 60 cm with a maximal field of view of 46 cm. Both the gantry and CT table can translate, 35 cm and 150 cm respectively.

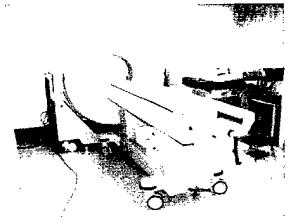

Figure 1: Mobile CT Gantry and Table

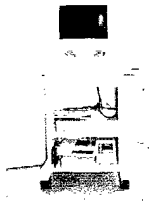

Figure 2: Operator's Workstation

In the operating room, the patient is placed on the CT table. Sterile plastic drapes are applied to the opening of the gantry aperture. An initial scanogram is taken to locate the desired vertebral level of the spine. During the procedure, the gantry can be moved away from the table to allow complete access to the patient. The gantry is re-docked for scanning as needed for intraoperative visualization. The preparation and CT scanning time averages 15-20 minutes per series. The Radiation Safety Office determined that personnel must either wear lead protection or remain at least 12 feet from the center of the gantry during scanning. The operator's workstation is placed outside a 12-foot perimeter. A photograph of the CT scanner in use in the operating room is shown in **Figure 3**. A diagram of the operating room layout is shown in **Figure 4**.

Figure 3: Mobile CT in Operating Room

The mobile CT has been used for over 100 procedures at our institution in the operating room and the interventional suite. In the operating room, 4 intracranial and 17 complex spinal procedures were performed. Intracranial cases involved 4 pediatric patients with subcortical glial tumors. Spine procedures included 7 transoral decompressions and 10 spinal tumor resections—2 extrapharyngeal, 5 thoracic, and 3 lumbosacral. In the neurointerventional suite, more than 30 percutaneous vertebroplasty procedures have been done. Other uses of the mobile CT scanner include radiation treatment planning, and use in the ICU.

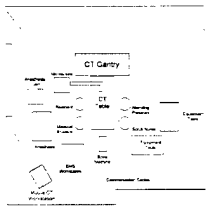

Figure 4: Operating Room Layout

RESULTS

Spinal Neurosurgery

In 6 of the 17 spinal neurosurgical cases at Georgetown University Medical Center, the CT provided information that altered the course of the surgery, including: 2 cases of more complete tumor resections, 3 cases of more complete ventral decompression of the brainstem, and one case of a correction of a slipped/rotated transverse process hook. There were no clinically detectable complications from the added use of CT.

Case Study

A 42-year-old woman with severe, deforming rheumatoid presented with spastic quadriparesis and numbness. Pre-op MR images of the cranio-cervical junction revealed basilar invagination with brainstem compression. The patient underwent a transoral odontoidectomy (**Figures 5, 6, and 7**).

Figure 5:
Intraoperative Scanogram

The initial scanogram showing occipito-cervical stabilization and C3-4 anterior spine plate from prior surgery, placement of instrumentation for transoral exposure, and patient placement in halo vest.

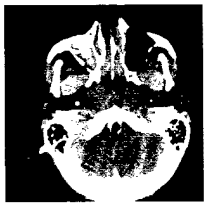

Figure 6: Initial Intraoperative CT

After initial resection, intraoperative axial CT scan revealed continued compression of the brainstem by a fractured portion of the odontoid (long arrow) obscured from direct visualization by pannus and resection cavity (short arrow).

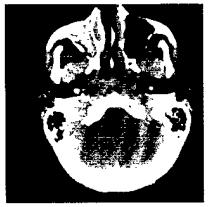

Figure 7: Final Intraoperative CT

After further resection, intraoperative CT scan verified complete odontoid resection. Post-operatively, the patient had return of strength and resolution of her brainstem symptoms.

Figure 8-A

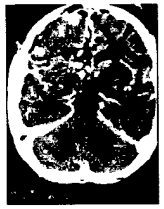

Figure 8-B

Figure 8-C

Figure 8-A: Pre-operative axial MRI showing enhancing lesion in the right lateral ventricle resulting in ventricular dilation on the right. **Figure 8-B:** Intra-operative contrast CT scan showing transcallosal approach, patties in resection bed, and no residual enhancing tumor. **Figure 8-C:** Post-operative MRI showing no residual enhancing mass, and resolution of ventriculomegaly.

Advantages and Disadvantages of Mobile CT in Spine Surgery

Advantages:

- confirmation of vertebral level with scanogram
- good visualization of bony pathology
- more specific surgical approach
- intraoperative imaging as surgery progresses
- verification of surgical correction of pathology before surgical closing
- mobility of CT scanner

Disadvantages:

- increase in OR time and cost
- need for additional trained staff
- risk of ionizing radiation exposure
- limited patient positioning

Advantages and Disadvantages of Mobile CT in Intracranial Surgery

Advantages:

- tracks soft tissue changes after craniotomy and dural opening
- extent and location of residual enhancing tumor easily identified despite other materials in the surgical bed
- verification of resection before closing
- tumors retain contrast long enough to obtain multiple scans without additional dye
- verifies absence of deep bleeding prior to breaking sterile field
- cost profile better than fixed intraoperative scanner

Disadvantages:

- not currently integrated with frameless navigation (but easy to do so)
- air/tissue interfaces limit resolution
- lesion must be enhancing for good visualization
- limited patient positioning
- increases OR time

Intracranial Neurosurgery

We operated on four patients, ages 3-17, with astrocytomas. Three were thalamic, and one was based primarily in the caudate nucleus. The approach to the basal ganglia was transcallosal in three, and transtemporal in one. Specific observations on the intraoperative use of the portable CT scanner included its overall facility, any additional operative time required, the overall quality of images, intraoperative decisions made based on the images, and any problems associated with its use. The CT scanner was helpful in limiting the dissection of the hypothalamic and midbrain regions and in localizing remaining abnormal tissue. The scans allowed informed decisions about leaving margins of tumor which were adjacent to vital structures, but did not prove to be a decisive factor in providing a complete resection.

Case Study

F.E. was a 12 year old male with tuberous sclerosis and a seizure disorder, both diagnosed at 6 months of age. He underwent a transcallosal resection of an intraventricular giant cell astrocytoma at 2 years of age. He remained tumor free until one year prior to surgery, when imaging showed a recurrence. The mass then showed progressive growth resulting in dilation of the frontal horn of the right lateral ventricle (**Figure 8-A**). A mesial frontal mass grew during the same time interval. On physical examination, the patient was moderately mentally retarded and non-verbal with stigmata of tuberous sclerosis. He had no focal neurological deficits.

Intraoperative CT showed two enhancing lesions (**Figure 8-B**). The obtained scans showed the two lesions well, and placement of patties prior to the scans confirmed the location of abnormal tissue to be removed. After surgery, he had no new neurological deficits, and imaging showed no residual tumor (**Figure 8-C**).

CONCLUSION

At Georgetown, the mobile CT has been used successfully in the operating room, the interventional suite, radiation medicine, and the ICU. The CT may not be necessary for simple surgical procedures but we believe that it will be an indispensable imaging modality for select complex spinal and intracranial procedures to improve patient outcomes. In the OR and the interventional suite of the future, it is one of several imaging modalities that should be available "on demand" for intraoperative use.

ACKNOWLEDGEMENTS

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10.3.6 Kim 2000: Simulated performance ...

Poster is reproduced on the next page. Presented as part of a demonstration at the RSNA conference Nov-Dec 2000 in Chicago, IL.

Simulated Performance of Radiotracer-Guided Breast Biopsy: *System Concept*

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INTRODUCTION

Purpose: To demonstrate interventional methods using molecular image guidance.

Radiology has lagged behind other medical disciplines in adapting molecular approaches to health care delivery. Although radiotracers are currently available that can image relevant biochemical features (e g , tumor proliferation, apoptosis, receptor density, glucose utilization, multi-drug resistance), there are no universally accepted methods to perform biopsy based on these radiotracer images. The dearth of biopsy-ready molecular imaging methods represents a barrier to development of minimally invasive surgery techniques

A collaborative multi-center program has been established, involving two university-based medical centers (Georgetown University and Harbor-UCLA) with strong image-guided interventional initiatives, and a private company with proprietary techniques for image-guided biopsy using positron and single-photon radiotracers (PEM Technologies). This team is developing interventional approaches to molecular imaging, using modern techniques in position sensing that provide a virtual reality approach to needle localization. Our initial clinical results (for single photon imaging) are described, with breast biopsy (scintimammography) as the first clinical application. A similar approach is being implemented for positron image guidance of breast biopsy

Scintimammography (SMM) has been shown to be sensitive in the detection of cancer [1]. In breast cancer, as in nearly all oncology, the provisional diagnosis of cancer must be confirmed by tissue diagnosis via biopsy or open surgery. For masses or abnormal mammograms, biopsy is straightforward. However, if a mass is palpable, there is little clinical need for SMM. We therefore sought a method of performing biopsy that would be appropriate for use with non-palpable cancers, which might be detectable only on the basis of SMM.

Prior methods employed for SMM-guided biopsy include the use of orthogonal views and non-imaging probes. Orthogonal views typically included the lateral view and an anterior view. Although the lateral view is satisfactory for detecting most cancers, the anterior view has the drawback of cardiac "shine-through" which can obscure subtle lesions. Non-imaging probes are difficult to use for deep or subtle lesions, and do not provide critical depth information. An approach was selected that was similar to the classic stereotactic methods employed by x-ray guided biopsy. This approach was first described by our group at Society of Nuclear Medicine 2000, and is simulated in this InfoRAD exhibit as an interactive demonstration.

METHODS

The approach employed is a variation of the classic off-axis technique commonly used in x-ray mammography to perform biopsy. The lateral view is first performed, in order to select the lesion for targeting, and then two off-lateral views are taken to provide depthinformation. In order to immobilize the breast for biopsy, a device was built (Figure 1) that incorporated many of the features that are standard in prone breast biopsy x-ray mammography platforms. This device consisted of a breast compression stand that fit under a standard scint imammography table (i.e., prone table with cutout for lateral views of the dependent breast). The compression stand was capable of quick release, and motorized compression and release that could be actuated by either hand or foot control. The compression paddles were fenestrated with holes separated by approximately 3 mm. An electronic readout provided the compression distance.

Figure 1.
Breast Compression Device
Compression device immobilizes breast for image-guided biopsy.
Note: For investigative use only, not FDA approved

So far, we have tested the device on an ADAC single head camera. The procedure we have followed began with a calibration of the gamma camera's position linearity, by imaging with radioactive markers placed on the medial and lateral compression paddles. Positions of the markers as seen by the gamma camera were measured with the ADAC annotation procedure, which provides a screen coordinate. After calibration, the breast was placed in mild compression and a lateral view was obtained for 10 minutes. The compression depth was measured from the compression device readout. For this lateral view, the paddles were placed parallel to the gamma camera face. The lateral view image was inspected for the presence of suspicious lesions. If any suspicious lesions were detected, radioactive markers were placed on the medial and lateral paddles in order to bracket the suspicious lesion. The medial marker was placed on the inferior-anterior medial aspect of the patient's breast (henceforth referred to as the IAM marker), and the lateral paddle marker placed on the superior posterolateral aspect of the patient's breast (henceforth referred to as the SPL marker). The locations of the markers were again measured using the annotation procedure. The gamma camera head was then rotated through two symmetric angles of up to 15 degrees, and the positions of the markers and of the lesion were measured (using the annotation procedure).

A classic stereotactic algorithm was then applied in order to provide the user with the predicted depth of the lesion from the lateral paddle, and the X and Y position of the lesion as measured from the SPL marker. This stereotactic algorithm was implemented on a Palm Pilot. The software is for investigative purposes only, and has not been cleared by the FDA. Although in principle a biopsy could be performed from the medial side, the current configuration of the prone scintimammography table did not permit ready access from the medial aspect of the breast, and changes would be needed to the table if medial approaches were needed.

Using the coordinates provided to the user from the Palm Pilot, a standard hook wire was placed into the expected location of the lesion, compression was released, and the patient was sent to surgery for needle-localized biopsy.

TESTING

The algorithm and procedure described above was tested with phantoms prior to clinical studies. Phantoms were prepared by soaking small cotton balls in blue dye and Tc-99m solution. The cotton balls were then placed in a breast phantom. The cotton balls were varied in size from 5 mm to 2 cm. Using the procedure discussed above, hooked wires were placed under gamma camera guidance, and visual inspection was then performed to determine if the wire was located within the region of blue dye. Under an IRB-approved clinical protocol at Harbor-UCLA, two patients have had biopsies with the procedure described above.

RESULTS

In twenty phantom experiments, the needle was localized in the region of blue dye every time, suggesting high accuracy. In the two pilot patient studies performed, a cancer was identified in one patient that was removed surgically using image guidance from the procedure described above. This cancer was not visible under ultrasound or x-ray mammography. A second patient study revealed apocrine metaplasia.

DISCUSSION

Figure 2.
Axillary Imaging with PEM
Image of tumor in axillary portion of the breast.

The stereotactic method appears to be accurate in localizing lesions for biopsy with single photon cameras. Phantom studies suggest that the method is highly accurate for both large and small lesion sizes. Pilot clinical trials have too few patients to provide statistically significant information as to the accuracy of the technique at this time. The collaborative group will proceed along several lines to the next steps in this project. Additional patient at Harbor-UCLA will be studied using the single photon camera methods described in the methods section above. The virtual needle program developed in the accompanying workstation simulation will be adapted to actual patient studies using both single photon and positron emitting radiotracers.

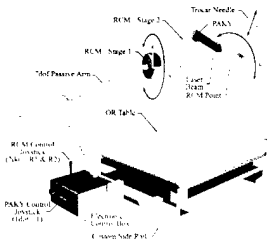

Figure 3: Needle Driver Robot
Footnote: Urology Robotics Laboratory
(Dan Stoianovici Ph.D.)
and the Computer Integrated Surgical Systems & Technology Engineering Research Center
(Russell Taylor Ph.D.)
at Johns Hopkins

The positron imaging studies wil be implemented using PEM Technologies' positron emissior mammography camera, which i currently undergoing clinical trial at Wake Forest University (Figure 2) [2]. The coordinates provided by the off-axis views wil be sent to a robotic device currently being evaluated a Georgetown University fo automated biopsy and image guided lesion resection, as a firs step in molecular-guidec minimally invasive therapy (Figure 3).

SUMMARY

A method of stereotactic localization has been adapted to nuclear medicine, which appears highly accurate in phantom studies. This work represents a first step in implementing interventions based on molecular imaging studies.

ACKNOWLEDGMENTS

This work was partially supported by the U.S. Army under grant DAMD17-99-1-9022 and by the Department of Energy grant FG02-97ER82449. The content of this poste does not necessarily reflect the position or policy of the U.S. Government.

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10.3.7 Levy 2000: TIPS ...

Poster is reproduced on the next page. Presented at the RSNA conference Nov-Dec 2000 in Chicago, IL.

TIPS: Feasibility of a Single Puncture Percutaneous Anterior Abdominal Access

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Filip Banovac, MD[1,2] Sumiyo Onda, BS[2]
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Abstract

The goal of this study is to determine if:

1) CT imaging can be used to plan and guide a TIPS procedure from an anterior percutaneous approach and
2) an anterior percutaneous approach is technically feasible.

Transjugular intrahepatic portosystemic shunt (TIPS) creation has become an important therapeutic procedure for the management of the complications of portal hypertension. The intrahepatic shunt consists of a percutaneously created conduit between a hepatic vein and a portal vein which is structurally supported by a metallic stent. Diversion of portal venous return results in amelioration of portal hypertension. Variceal bleeding, intractable ascites, and hepatopulmonary syndrome are some of the complications of portal hypertension which have been shown to improve or resolve following TIPS. Percutaneous TIPS creation from an anterior abdominal approach has been accomplished between a portal vein branch and the IVC, although this approach may preclude liver transplantation.

Typically, the most time consuming and technically challenging step in the TIPS procedure is the successful transhepatic puncture of the portal vein originating from the hepatic vein. Most often, the portal vein is successfully punctured after several needle passes under fluoroscopic control. In a large survey, an average mortality of 1.7% was reported for institutions performing more procedures, while a 5% mortality rate was observed where fewer than 150 procedures were performed. Puncture of the hepatic capsule with the large Colapinto needle with resulting exsanguination has been reported to occur in at least 4% of patients. Difficult procedures or procedures performed by inexperienced operators require prolonged fluoroscopic exposures, and a greater number of puncture attempts may increase the likelihood of intraperitoneal hemorrhage. Fluoroscopic exposure exceeding one hour in duration may result in mild radiation toxicity including skin erythema or ulceration.

Conclusions:

1) a creation of a TIPS shunt from an anterior transabdominal approach is technically feasible.
2) A catheter pullback technique allows successful placement of a catheter for subsequent shunt creation for this approach.

Materials and Methods

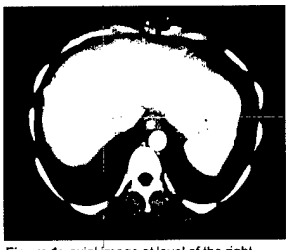


Figure 1: axial image at level of the right hepatic vein (arrow) with localizing cursors

Image Analysis:

Abdominal CT scans obtained on 9 patients with no history of cirrhosis or hepatic metastases, and MRI studies on 5 patients with known cirrhosis were loaded on a Siemens MagicView workstation for retrospective multiplanar image reformation (MPR). CT studies and MRI studies were obtained following the intravenous administration of contrast.

1) The right hepatic and portal veins were identified on the axial images and an anteroposterior linear cursor was positioned on the right hepatic vein within three centimeters of its origin **(Figure 1).**

2) Cranio-caudal and mediolateral angles were obtained on sagittal and oblique images respectively **(Figure 2 and 3).**

3) The portal to hepatic vein distance and skin to hepatic vein distance were measured on an oblique reconstructed image. Organ interposition was documented **(Figure 4).**

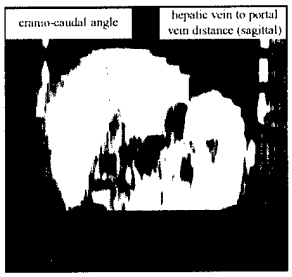


Figure 2: Cranio-caudal angle measured on the sagittal image

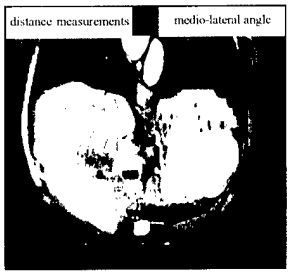


Figure 3: the medio-lateral angle was measured from the oblique images. This angle shows the path needed to connect the hepatic vein and the portal vein via a transabdominal percutaneous puncture.

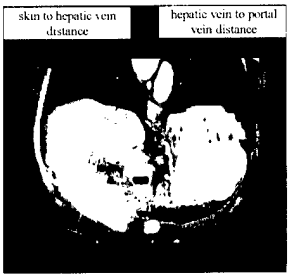
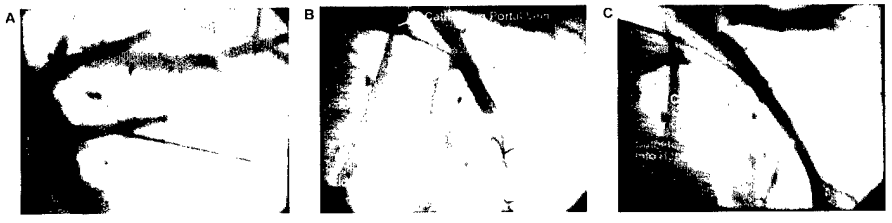


Figure 4: oblique image of the liver in a plane that contains both the hepatic and the portal vein. Distances from the hepatic vein to the skin surface and hepatic vein to portal vein were measured as demonstrated here.

Ex Vivo Porcine Procedure Model (Figure 5)

In the ex vivo experimental TIPS access procedure, ex vivo livers from 50kg pigs were provided and the portal and hepatic veins flushed with saline. Dilute barium sulfate contrast material was injected using a catheter tipped syringe into the hepatic veins and portal veins. Right portal and hepatic vein branches were visualized and directly punctured under fluoroscopic guidance using a 21 gauge needle **(Figure A)**. A .018 guidewire was passed into the portal vein and retrieved from the exposed portal vein for control purposes. A 4F Micropuncture catheter was then advanced over the guidewire from the portal vein confluence until the tip emerged through the liver capsule. The catheter tip was then withdrawn slowly while the tip of the guidewire was simultaneously advanced (catheter pullback technique) until the wire could be seen advancing into the target hepatic vein lumen **(Figure B)**. The catheter was exchanged for a diagnostic 5F catheter and intraluminal position of the catheter was confirmed by contrast injection **(Figure C)**.



Results

Abdominal CT scans obtained on nine patients with no history of cirrhosis or hepatic metastases were retrospectively reviewed. A potential access route was considered satisfactory if the anticipated needle path did not intersect an organ.

In nine patients with normal livers, a successful anterior approach to the right hepatic vein and right portal vein was documented in seven patients. However, a successful middle hepatic vein to left portal vein approach could be drawn in only six patients. No suitable access was identified in a single patient.

Reasons for failed anterior approaches included interposition of the stomach, gallbladder, or colon, steep Cranio-caudal angle, inadequate opacification of the hepatic veins, and interposition of main portal vein between left portal vein branch and middle hepatic vein.

In the five cirrhotic livers studied, neither right nor left sided access was available in one patient. In the remaining four patients, right sided access was available in three, and left sided access was present only in the one remaining patient in the group.

Right Hepatic Vein/Right Portal Vein TIPS Approach

LIVER:	Skin->Hepatic Vein Distance	Portal Vein->Hepatic Vein Distance
NORMAL	151.5+/- 16.9 mm	48.6+/- 11.0 mm
CIRRHOSIS	166.9+/- 10.7 mm	44.8+/- 12.4 mm

Conclusions

The technical feasibility of an anterior abdominal percutaneous approach to TIPS creation has been demonstrated. Preoperative CT or MRI can identify potential anterior access routes for intrahepatic portosystemic shunts.

A catheter pullback technique allows successful placement of a catheter for subsequent shunt creation for this approach.

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10.3.8 Watson 2000: Three dimensional rotational ...

Poster is reproduced on the next page. Presented at the RSNA conference Nov-Dec 2000 in Chicago, IL.

Three Dimensional Rotational Angiography and Spiral CT for Monitoring Percutaneous Vertebroplasty: Initial Results

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[3] Imaging Science and Information Systems (ISIS) Center, Department of Radiology

Introduction

Percutaneous vertebroplasty is a relatively new interventional technique in which polymethylmethacrylate (PMMA) bone cement is injected into the vertebral body to strengthen the body and stabilize the spine. Indications for percutaneous vertebroplasty include painful osteoporotic and pathologic fractures. At Georgetown University Medical Center, the procedure is done in an interventional suite that accommodates bi-plane fluoroscopy, angiography, rotational angiography, and a mobile CT scanner. We have noticed that it can be difficult to see and be confident as to the amount of extravasation in some cases. For this reason we use a mobile CT in our lab to evaluate the patients during and after the procedure, and have gained experience with 3D CT reconstructions. Because we found 3D CT to he helpful we sought methods to produce 3D images with the C-Arm and validate those findings by comparing with 3D CT. The chosen approach was to use rotational angiography protocols as there are many similarities to CT data acquisition.

3D Rotational Angiography

Technical Aspects

There are numerous variables involved in producing high quality 3D images. These variables range from patient positioning and cooperation to acquisition parameters and isotropic voxel size.

The Patient

The region of interest has to be positioned in iso-center. The vertebral bodies have to be in the center of the imaging field. Strict cooperation from the patient is essential. Proper respiration and patient immobility will reduce unwanted artifacts.

The Acquisition

Before the acquisition is started a special form filter is placed on the collimator to produce a homogenous image. This filter will reduce the density changes associated with the imaging of the thorax and abdomen in a 200 degree arc. The proper program must be selected to insure an adequate image acquisition. The operator may chose both a rotation duration and dose (High/Low) as shown in Table 1.

Rotation Duration	Images	Dose
5 seconds	50	High/Low
8 seconds	80	High/Low
14 seconds	132	High/Low

Table 1. Rotational Programs

Image Post Processing

The images can be manipulated in 2 ways: Window Width/Level and Percentage Classifier. Slide tools are used for the adjustment of Width/Level, Opacity, and, Brightness. Percentage Classifier allows the user to designate colors for specific Hounsfield units in the image data (Figure 1) [Hounsfield 1979].

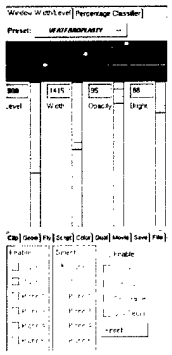

Figure 1. Processing Tools

Equipment

The room layout and equipment placement is shown in Figures 2-5. Figure 2 shows the interventional suite during a typical case. Figure 3 shows the patient and initial position of the C-Arm for a rotational angiography acquisition. Figure 4 shows the patient in preparation for a mobile CT spiral scan. Figure 5 is a diagram of the interventional suite.

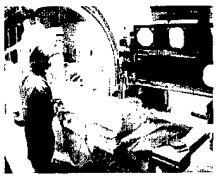

Figure 2.
Bi-plane Fluoroscopy

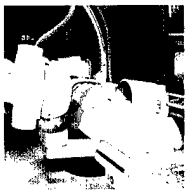

Figure 3.
C-Arm in Position
for Rotational Exam

Figure 4.
Preparing for
a Mobile CT Scan

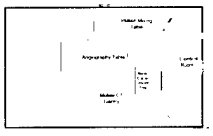

Figure 5.
Neuro-interventional Suite

Acknowledgements

This work was supported by the U.S. Army under grant DAMD17-99-1-9022. The content of this poster does not necessarily reflect the position or policy of the U.S. Government.

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Data Acquisition and Processing

Step 1: Vertebroplasty

The procedure is performed in the usual manner under fluoroscopic guidance [Watson 1999].

Step 2: 3D Rotational Acquisition

All acquisitions are done using the 33-cm Image Intensifier zoom format. Digital images are acquired using a 200-degree arc (100 degrees LAO to 100 degrees RAO, Cran/Caud 0 degree). This will produce 132 digital images (1024 x 1024 pixel). The high dose setting is used to compensate for the density differences.

Step 3: Image Transfer

Image transfer to the 3D workstation (Virtuoso) is accomplished via a dedicated 10BaseT connection. The mobile CT images are transferred to a DICOM viewing station then transferred via the hospital's (LAN) local area network to the Virtuoso. See Figure 6: Hospital LAN.

Step 4: Image Processing

The image data is processed on the Virtuoso (Silicon Graphics O2 workstation & HipGraphics software). The Volume of Interest (VOI) is selected with an isotropic voxel size of less than 0.3 mm, a 256 x 256 matrix size is selected, and "High Quality" reconstruction is chosen (Figure 7). A modified cone beam CT reconstruction with convolution and a backprojection algorithm is used for the reconstruction of the rotational images [Feldkamp 1984].

Step 5: Image Review

Both the 3D rotational CT reconstruction and the CT images are loaded in to the volume viewer of the Virtuoso and reviewed simultaneously in a two view format as shown in the case studies below (Figures 8 and 9).

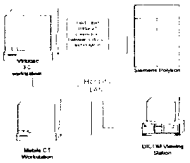

Figure 6. Hospital LAN

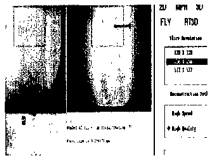

Figure 7. VOI Window

Tabulation of Cases

Percutaneous vertebroplasty procedures have been done at our hospital since 1997 and over 150 procedures have been completed. The mobile CT scanner was introduced in May of 1998, and has been used in over 25 cases. The mobile CT cases were reviewed by two neuroradiologists, and a tabulation of the results was created. Neuroradiologist 1 is the most experienced and did the procedures, and neuroradiologist 2 is trained in vertebroplasty and blinded to the patients. The data collection was done by the radiology technologist, who had knowledge of both the patient and the procedure.

The neuroradiologists reviewed both fluoroscopic and CT images on a personal computer-based viewing workstation. The images were sent from the mobile CT and fluoroscopy systems over a network using the DICOM standard. The information tabulated during the viewing of the images included: level or levels done, percent compression, and whether extravasation was better seen under fluoroscopy or CT (for epidural, epineural, paravertebral, disc, and venous regions). In this poster, images from two representative examples are shown.

From this tabulation, the following trends were observed. While extravasation is easily seen in the CT images, it is not always apparent in the fluoroscopic images. More specifically, extravasation into the epidural and epineural regions is easily visualized by CT. Venous and disc extravasation of PMMA is typically readily detected under fluoroscopy.

Case Study 1

Patient one is a 65 year old service station operator with severe pain in the lower back for 4 months. He has metastatic renal cell carcinoma with involvement of multiple vertebra and several pathological compressions. The chief source of pain seemed to be the L4 vertebra. Vertebroplasty was performed. The pain improved markedly. After the procedure, rotational anigography and CT scans were performed (Figure 8 a-d). Yellow arrows point to intradiscal extravasation, red to extravasation ventral and lateral to the vertebral body. The rotational angiography images are on the left and CT images are on the right.

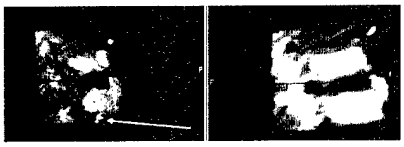

Figure 8a

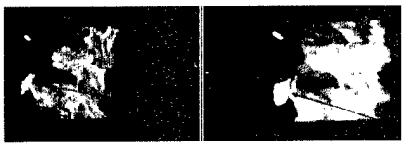

Figure 8b

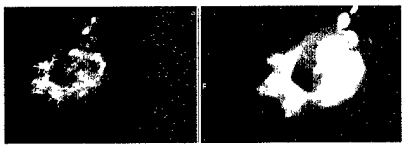

Figure 8c

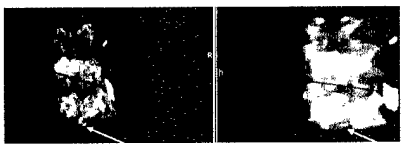

Figure 8d

Case Study 2

Patient two is a 78 year old woman with osteoporosis and a remote history of breast cancer. She had severe low back pain related to an L3 compression fracture and was treated with biopsy and vertebroplasty. After the procedure, rotational anigography and CT scans were performed (Figure 9 a-d). The pain improved markedly. The biopsy returned no evidence of malignancy. Yellow arrows point to intradiscal extravasation, red to extravasation ventral and lateral to the vertebral body, magenta to epidural extravasation, and blue to venous extravasation. The CT images are on the left and the rotational angiography images are on the right.

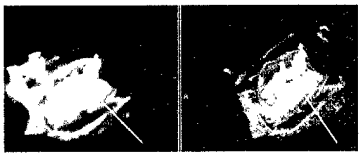

Figure 9a

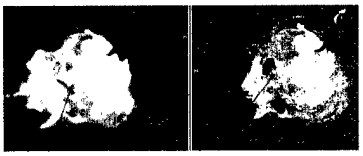

Figure 9b

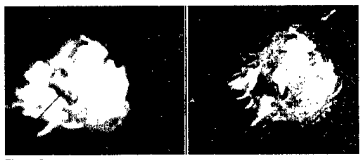

Figure 9c

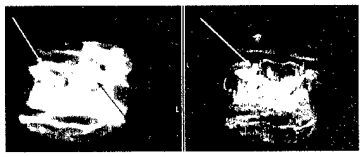

Figure 9d

References

Watson VE, Cleary KR, Lindisch D (1999) "Mobile CT assessment of needle placement and distribution of polymethylmethacrylate (PMMA) during percutaneous vertebroplasty." Scientific Exhibit, RSNA 1999, Chicago.

Feldkamp LA, Davis LC, Kress JW (1984) "Practical cone-beam algorithm." J. Opt. Soc. Am. A 1, 612.

Hounsfield, GEN (1979) "Computed medical imaging. Nobel lecture, Dec. 8, 1979." J. Computer Assisted Tomography 4(5) 665-674.

Conclusion

Both mobile CT and 3D images produced from rotational angiography techniques are accurate in the detection of various types of extravasation, the pattern of cement deposition within the vertebra, and can produce 3D models that are useful in diagnosis and teaching. CT produces slightly better cortical margin distinction and segmentation of bone from cement. The advantage of the rotational angiography technique is that sites performing vertebroplasty under fluoroscopic and digital XR need only one piece of equipment.

10.4 Protocol for robotically assisted nerve blocks

Protocol begins on the next page and is 20 pages long.

Number: _____
Date Received _____
Date Reviewed by IRB _____
Approved Deferred Disapproved

GEORGETOWN UNIVERSITY MEDICAL CENTER PROTOCOL FOR CLINICAL STUDY

1. **Title of Project:** Periscopic Spine Surgery: An Image Guided Robotic System for Precise Percutaneous Access

2. **Purpose of Project:** The purpose of this research study is to evaluate a robotic device to help with minimally invasive spine procedures including biopsy, facet and nerve blocks, vertebroplasty, discography, and radiofrequency and laser ablations. The robotic device consists of a mechanical instrument holder and driver and a computer-based control system. We are evaluating whether this device can assist the physician in placing and advancing instruments, such as needles, in the spine. We believe this device may increase the accuracy and efficiency by which these instruments are placed and manipulated, which may lead to better patient outcomes.

   According to the Robotic Institute of America, a robot is defined as "a reprogrammable, multi-functional manipulator". In this case, as will be explained in detail in Sections 8 and 9, the device is controlled by the physician through a joystick and a computer-based control system. The device is always under the direct control of the physician, and is never able to act on its own. For conciseness, we have chosen to call it a "robot", although a more complete description might be "a mechanical instrument holder and active driver".

3. **Principal Investigator:** Vance Watson, MD
   Director of Neurointerventional Radiology
   Department of Radiology
   3800 Reservoir Road NW
   CCC Ground Floor
   Washington DC 20007
   Telephone Number: 202-784-3420

4. **Location of Study:** Neurointerventional Suite, Georgetown University Medical Center. The address is the same as in item 3. The site director is Dr. Watson.

5. **Names and roles of co-investigators:**
   Kevin Cleary, PhD, ISIS Center, Radiology Department, 202-687-8253.
   Matthew Freedman, MD, ISIS Center, Radiology Department, 202-687-7948.

Dr. Cleary is the principal investigator of the Periscopic Spine Surgery project, which is funded by

the U.S. Army Medical Research and Materiel Command. Under this project, the robotic device is being developed in collaboration with The Urology Robotics Laboratory of the Johns Hopkins Medical Institutions. Dr. Cleary also serves as the technical lead for the project. Dr. Freedman is the clinical director of the ISIS Center and a co-investigator on the Periscopic Spine Surgery. He will provide direction to the project and serve as a link between the clinical and technical teams.

6. **Study information** required for Georgetown and Army protocols is listed here.

Estimated start date: November 2000

Estimated completion date: November 2001

Estimated project duration: 1 year

Estimated total number of subjects: 100 — 50 with the robotic device and 50 without.

Age range of subjects: subjects must be greater than 18 years of age.

Inclusion/exclusion criteria: patients who are pregnant as determined by laboratory test and clinical history are excluded. This exclusion is due to the procedures being performed, not the use of the robotic device. These procedures have the potential for damaging the fetus due to ionizing radiation and the use of anesthesia. There are no other exclusion criteria except for the age limitation noted above.

As with patients having this procedure without the robot, as part of the preparation process on the day of the procedure a member of the medical staff asks the patient if there is any possibility of pregnancy. If the patients replies that pregnancy is not possible we proceed with the procedure. If there are questions regarding a patient's pregnancy status, urine testing is done at that time. The test results are typically available within one hour. The urine collection procedure is included as Appendix A. In the consent form, patients are advised to avoid becoming pregnant for at least 1 month after participation in the study. This advice applies to all female patients who undergo these procedures, not just those cases involving the robotic device. This advice is a routine part of good clinical practice.

Estimated total numbers of controls: 50 (patients who have the procedure done in the standard method without the robotic device will be put in the control group)

Source of subjects: patients will be recruited from within Georgetown University Hospital and affiliated outpatient practices and the existing practice of Dr. Watson.

7. **Grant support for project:** U.S. Army Medical Research and Materiel Command, grant DAMD17-99-1-9022. The protocol and consent form will be reviewed by the Human Subjects Research Review Board (HSRRB) of the U.S. Army after approval at Georgetown.

There is no pharmaceutical company support for this project.

8. Brief historical background of the project with reference to the investigator's personal experience and to pertinent medical literature.

Percutaneous instrument placement for spinal procedures is technically very demanding and requires extensive training to achieve efficiency and accuracy. The principal investigator, Vance Watson, MD, performs this task as a routine clinical activity. A robotic device that could assist the physician in instrument placement and manipulation would be of great utility in many spinal procedures such as biopsy, facet and nerve blocks, vertebroplasty, discography, and radiofrequency and laser ablations if it increases the accuracy of initial alignment and the subsequent passage along the planned trajectory.

A robotic device for percutaneous renal access using "C-arm" fluoroscopy has been developed by the Urology Robotics Laboratory at Johns Hopkins Medical Institutions. At Johns Hopkins, this device has been used successfully for over 12 patients undergoing percutaneous nephrolithotomy[1] in the Urology Department under the research direction of Louis Kavoussi, MD.

Georgetown has an existing Army grant (Periscopic Spine Surgery: DAMD17-99-1-9022) to advance the state-of-the-art in image-guided and minimally invasive spine procedures. This grant was recently amended to include Johns Hopkins as a subcontractor to Georgetown and begin a collaboration between the two research groups. The focus of this collaboration is to apply the robotic device to percutaneous instrument placement and manipulation for spine procedures. The long-term goal is to develop new equipment and techniques for robotically assisted, minimally invasive, percutaneous spine procedures.

A subcontract has been issued to Johns Hopkins from Georgetown for this collaboration. The statement of work for the subcontract is attached as Appendix B. Note that while the subcontract states the robotic device will be adapted for vertebroplasty, this has been expanded to cover robotic needle spine procedures by agreement of both Johns Hopkins and Georgetown, as the requirements for the robotic device are virtually identical for all needle spine procedures. The principal investigator at Johns Hopkins is Dan Stoianovici, PhD, a mechanical designer and expert in medical robotics.

The robotic device consists of:

1) a passive positioning and supporting arm very similar to locking arms used to adjust headholders, drill mounts, or operating room microscopes
2) an active remote center of motion orientation mechanism. This is essentially a targeting device, which in this study will be controlled by the physician using a joystick. The physician will have a direct view of the remote center of motion mechanism while using the joystick. Remote center of motion means that the needle tip can be considered a fixed point and the mechanism can move under joystick control so as to reorient the needle as desired without moving the needle tip. .

[1] Stoianovici, D., L. L. Whitcomb, et al. (1998). A Modular Surgical Robotic System for Image Guided Percutaneous Procedures. MICCAI 98, Cambridge, MA, Springer Verlag, 404-410. This article is attached as Appendix C.

3) a radiolucent end-effector, which drives the needle forward in a controlled path under direct joystick control of the operator.

A drawing of the robotic device is shown in Figure 1. The radiolucent end-effector is shown in Figure 2. The robotic device performing percutaneous renal access in the Urology Department at Johns Hopkins Medical Institutions is shown in Figure 3.

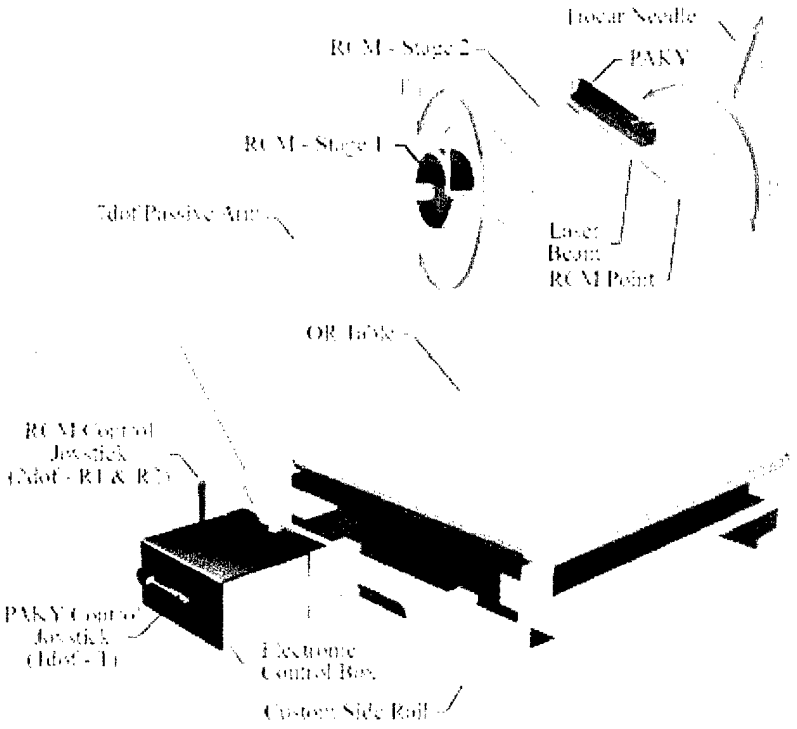

Figure 1: Robotic device showing mechanical arm and joystick control
(Courtesy of Dan Stoianovici, PhD, Urology Department, Johns Hopkins Medical Institutions)

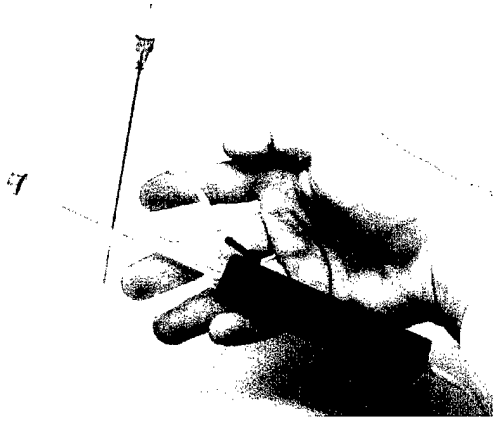

Figure 2: The radiolucent end-effector
(Courtesy of Dan Stoianovici, PhD, Urology Department, Johns Hopkins Medical Institutions)

Figure 3: The robotic device performing percutaneous renal access at
Johns Hopkins Medical Institutions.
(Courtesy of Dan Stoianovici, PhD, Urology Department, Johns Hopkins Medical Institutions)

While this device has been developed to place a needle for percutaneous renal access, it is also suitable for placing any thin tubular-shaped instrument in various other regions of the body. At Georgetown University Medical Center, we plan to adapt this device for percutaneous spine procedures. The details of our plan will be covered in the next section.

9. Plan of study.

This section includes an introduction to the research program, an explanation of how the robotic device will be used in percutaneous spine procedures, and human subjects management for the clinical study.

9a. *Introduction*

Currently, percutaneous spine procedures are performed by freehand passage of instruments (such as a needle or trocar[⊕]) from the skin surface to the spine. Based on imaging modalities such as X-ray fluoroscopy and/or computed tomography, the physician plans a trajectory from the skin to the target in his/her mind. The physician then aligns the instrument in his/her hand and inserts it

[⊕] For the spine procedures proposed here, the instrument can be a trocar (thin hollow straw-like device through which other instruments including needles can later be inserted) or a needle.

part of the way towards the target. The instrument is then released and the instrument position is checked with imaging to confirm that it is on the correct target trajectory. As required, the physician adjusts the instrument in a free hand manner and then advances further. This process of "advance and check" is repeated until the instrument is adjacent to the portion of the spine of interest.

The main problem with this approach is that the unaided human system has limitations in accuracy when initially lining up the instrument and then staying on course. Additionally, when the physician lets go of the instrument the instrument often drifts or tilts away from the desired path due to gravity (particularly in percutaneous procedures such as vertebroplasty, where a large gauge trocar is employed). An analogous non-medical example of this problem is drilling a straight hole in wood with a handheld drill versus a bench-mounted drill press or industrial robotic system.

Therefore, our long-term goal is to develop a robotic system that is directly linked to the medical images (for example, X-ray fluoroscopy or computed tomography) and helps the physician guide the instrument to the target in a more direct and controlled manner. This long-term goal will be achieved through a series of increasingly more complex prototype systems and clinical evaluation.

In the initial stage proposed here, we plan to modify the existing robotic system developed in the Urology Robotics Laboratory at Johns Hopkins Medical Institutions and described in the previous section. This robotic system has been used at Johns Hopkins for percutaneous renal access, and we plan to modify it slightly for percutaneous spine procedures. The modifications are: 1) providing a means to mount the robot on the fluoroscopy table in the neurointerventional suite; and 2) modifying the end-effector so that it can hold the instruments used for spine procedures and advance them under the physician's direct control.

Photographs showing the neurointerventional suite, fluoroscopy table, and a typical percutaneuos spine procedure (vertebroplasty) as performed by Dr. Watson are shown in Figure 4. From the right side photograph of Figure 3, one can visualize the freehand nature of the procedure. As described above, we plan to mount the robotic system from Johns Hopkins on this fluoroscopy table (using an arrangement similar to that shown in Figure 1). The robot will then be used to help line up and advance the instruments in the spine as described next.

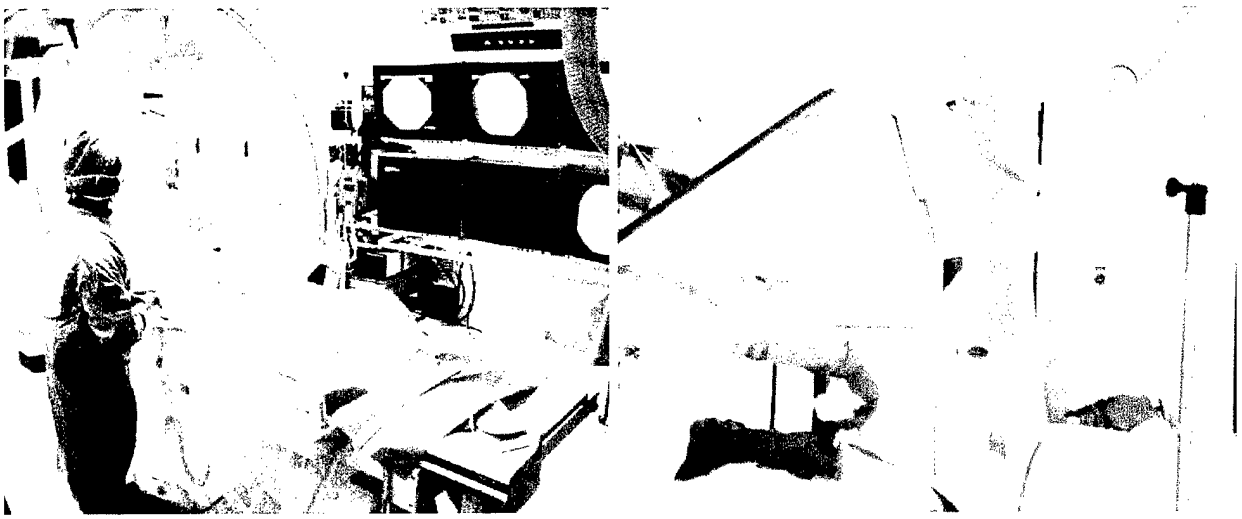

Figure 4: Interventional suite and fluoroscopy system at Georgetown (left hand side), typical spine intervention (vertebroplasty: right hand side)

9b. *Use of the robot in percutaneous spine procedures*
The spine procedure will be carried out as follows. The procedure will follow current clinical practice, except the robotic device will be used to help position and manipulate the instrument. How the robot will be employed is explained in the next three paragraphs, but a summary will be given first. The physician maintains control of the robotic device at all times as the robot only moves in response to the joysticks, which are manipulated by the physician to move the robot. The instrument held by the robot is placed manually at the skin entry point, and the robot is then used by the physician under joystick control to orient and advance the instrument.

The robotic device will be mounted on the fluoroscopy table on a hinged mount, which can be easily moved out of the way to allow the patient to be positioned on the table. Once the patient is positioned, the hinged mount will allow the robotic device to be positioned directly above the vertebral level of interest. The instrument (needle or trocar) to be used in the procedure will then be inserted by hand into the robot's end-effector and secured. The skin entry point on the patient will be identified as in current clinical practice, and the tip of the instrument will be manually placed at the skin entry point. The robot will now be used to help orient and advance the instrument towards the spine.

Using the fluoroscopy images and other pre-procedure images such as computed tomography studies or x-ray films, the physician will plan the trajectory from the skin to the target in his/her mind. The physician will then use a joystick connected to the robot's control computer to orient the instrument along the desired trajectory while precisely maintaining the tip of the instrument on the skin entry point. The physician will remain in direct control of the robot during this step, can discontinue use of the robot at any time if desired, and revert to the current free hand procedure.

Once the desired orientation of the instrument has been attained and verified, the physician will then use another joystick to slowly advance the instrument towards the spine. In addition to directly controlling the robot through the joystick, the physician will be able to closely watch the

operation of the robot at all times, and can also continuously monitor the advancement of the instrument towards the spine using fluoroscopy as desired. Once again, the physician will remain in direct control of the robot during this step, can discontinue use of the robot at any time if desired, and revert to the current freehand procedure.

9c. *Human subjects management*
The initial human trials will focus on nerve and facet joint injections. This procedure is a very common treatment for back and nerve pain. The instructions to patients undergoing the procedure are included as Appendix D. The surgical consent form used at Georgetown is included as Appendix E.

The outcome measures for this study are: 1) accuracy of needle placement and 2) pain relief. These measures will be described in more detail below.

The total number of patients we plan to enroll in this study is 100 — 50 with the robotic device and 50 without. The statistical justification is given in Section 11, Statistical Analysis.

Although this device has been used successfully in the Urology Department at Johns Hopkins, this study will be the first use of the device in the spine. Therefore, a Data Monitoring and Patient Safety Board has been formed to review the results of the first 20 patients (10 with, 10 without the device). This Board consists of William Lauerman, MD, an orthopedic spine surgeon at Georgetown, and Fraser Henderson, MD, a spinal neurosurgeon at Georgetown. Their resumes are included in the package submitted to the Army HSRRB.

After the first 20 patients, the results will be compiled and presented to the Data Monitoring and Patient Safety Board for review of safety and efficacy. The results will consist of the average accuracy with and without the robotic device, the change in pain scores, and any complications observed. This Board will have the power to stop the study or suggest modifications.

9d. *Outcome measures: accuracy of needle placement*
The accuracy of needle placement will be measured in the following manner. At the beginning of the procedure, the attending radiologist will annotate lateral and A/P fluoroscopic images with an arrow to indicate the desired target location. These images will be saved as digital images. Example images annotated this way are shown in Figures 5a and 5b. When needle placement is complete, lateral and A/P fluoroscopic images will also be saved as digital images as shown in Figures 6a and 6b. Each pair of images will be imported into Adobe Photoshop (an image-editing software application) and aligned on top of each other. Then, the measuring tool in Photoshop will be used to measure the distance from the needle tip to the target arrow. We anticipate these distances will be in the range of 0 to 5 mm.

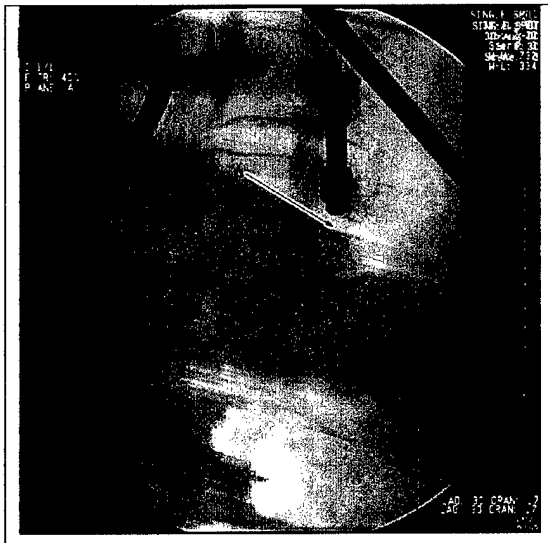

Figure 5a: A/P fluoroscopic image with arrow

Figure 5b: Lateral fluoroscopic image with arrow

Figure 6a: A/P fluoroscopic image with needle

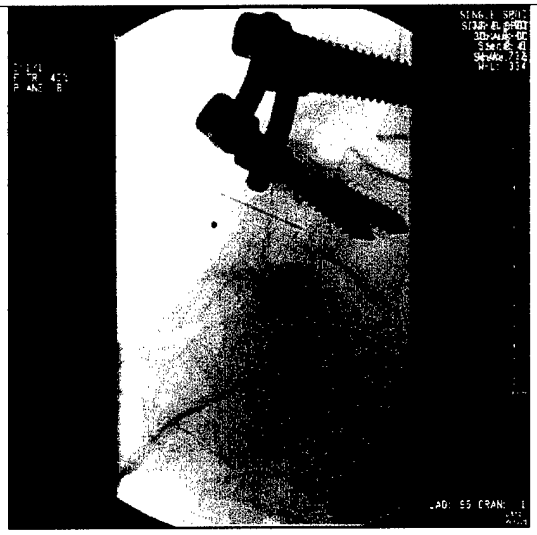

Figure 6b: Lateral fluoroscopic image with needle

9e. *Outcome measures: pain relief*

Pain quality will be assessed using the well-validated short-form of the McGill Pain Questionnaire [Melzack 1987], modified to assess back pain. This measure assesses the quality of pain by asking patients to rate the intensity of 15 verbal descriptors of pain. Patients use a 0-3 rating scale to perform this task. Patients are also asked to rate their pain intensity on a 0-5 numeric rating scale with each number anchored with a verbal descriptor of pain (e.g. 0=no pain, 5=excruciating). Three summary scores are derived from this measure: a sensory score derived by summing the first 11 items, an affective score derived by summing items 12-15, and a Present Pain Index represented by the score on the numeric intensity rating scale. At the beginning of this questionnaire, we will put a sentence explaining that we want are asking for information regarding

the patient's back pain only, so that patients with pain in other regions of the body will not report the intensity of this pain. The McGill short-form is easy to complete, and has demonstrated good correlation with the original widely used McGill Pain Questionnaire. The patient will be asked to complete this questionnaire just before the procedure and at 15-60 minutes after the procedure. Pain relief is often immediate in these procedures, and having the patient complete the questionnaire just after the procedure ensures the data will be collected. The questionnaire is included as Appendix F.

10. Validation and Training

To ensure that the robotic device is suitable for use in the spine and that the physician is capable of operating the device, the issues of validation and training must be addressed. The validation study and training of the initial operator will be done on cadavers and training of future operators will be done on an interventional phantom. The details are given in the next two sections (Sections 10a and 10b). Information on the handling of the cadavers is given in Section 10c.

10a. *Validation and Training of Initial Operator*
While this robotic device has been used in 27 cases for kidney access at Johns Hopkins Medical Institutions, it has not been used in the spine. Therefore, we need to validate that the device can be successfully applied to the spine. The validation will be done using cadavers and will be carried out by Vance Watson, MD, the principal investigator. The principal investigator is responsible for reporting the results of the validation and training study to the U.S. Army Human Subjects Research Review Board (HSRRB) prior to enrollment of human subjects in the clinical study.

The robotic device will be used to place needles in cadaver spines as follows:

1. 6 facet blocks
2. 6 nerve blocks

Since the clinical trials described in the previous section will focus on nerve and facet blocks, we will also focus on nerve and facet blocks in the cadaver study. The measure of success for the cadaver study will be accuracy of needle placement. This will be determined by placing BBs (small metal balls approximately 1 mm in diameter) at different levels in the spine near the target positions for nerve and facet blocks. The robotic device will then be used to place needles in an attempt to come as close to the BB as possible. The test will be considered successful if the needle tip is within 3 mm of the BB as measured on A/P and lateral fluoroscopy or on CT. The statistical justification in given in Section 11, Statistical Analysis. From preliminary cadaver tests, an example lateral fluoroscopy image is shown in Figure 7 and an example CT image is shown in Figure 8. Note that BBs are used in the cadaver study rather than annotating the fluoroscopy images as described in the human trials in Section 9d since BBs are less ambiguous as a target (but obviously cannot be used in human trials).

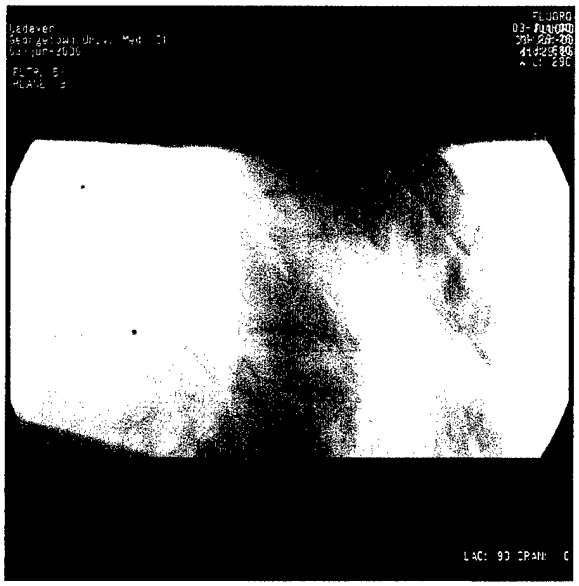

Figure 7: Example cadaver lateral fluoroscopic image showing bb and needle on left hand side

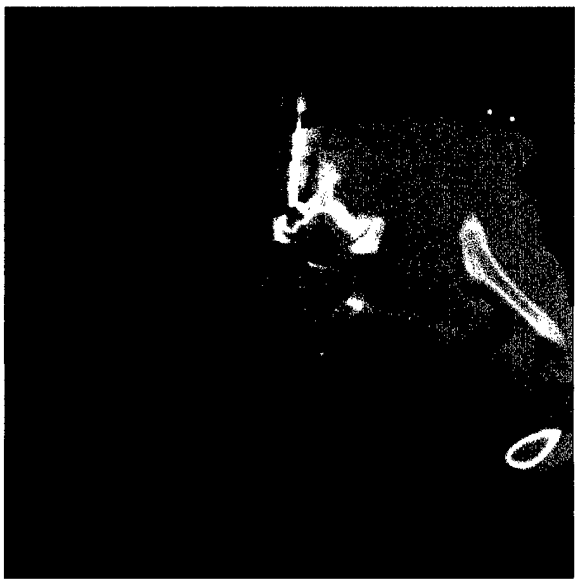

Figure 8: Example cadaver CT image showing bb, needle, and needle holder block

If the cadaver studies are successful, the device will then be used on patients by Dr. Watson. For the initial patient cases, engineering support will be present as an additional safety precaution (the mechanism is relatively simple and no problems are anticipated but this is an additional safety measure we will take). If the first 10 spine cases are completed by Dr. Watson without complications or any unusual events then we will consider training an additional physician operator as described below.

10b. *Training of Future Operators*

After the system has been validated by Dr. Watson as described above, he will serve as the trainer for any future operators. The training will be done on the interventional phantom shown in Figure 9. This phantom has been designed for training on interventional procedures and is extremely clinically realistic, both visually and in terms of the force sensations it provides.

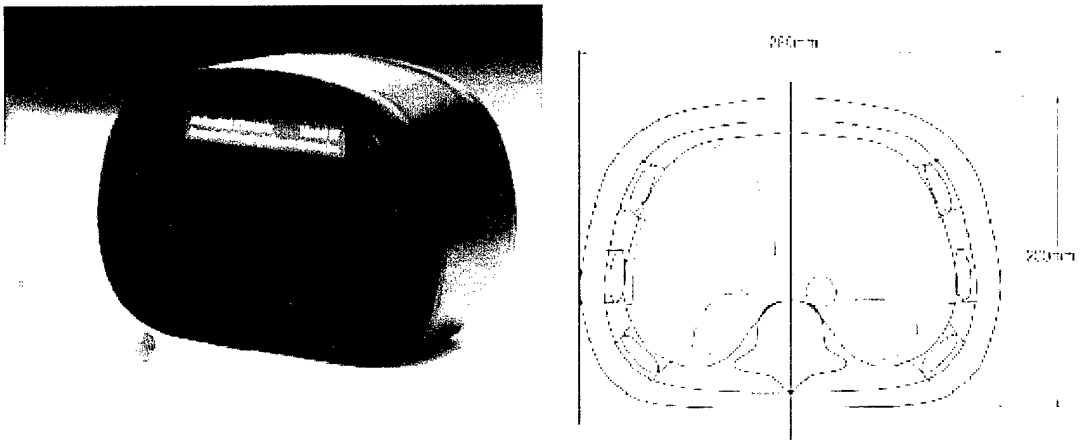

Figure 9: Interventional phantom (left hand side) and drawing of inside (right hand side)

The physician who is being trained will use the robotic device to place needles in the interventional phantom as follows:

1. 6 facet blocks
2. 6 nerve blocks

Dr. Watson will observe the training session. After the needle is placed, the needle position will be verified using fluoroscopy and CT (if necessary). Test records will be maintained by the research staff and verified by Dr. Watson. The test will be considered successful and the robotic device suitable for spinal needle placements if:

1. needle placement is judged to be as accurate as hand needle placement
2. no complicating factors such as multiple passes or excessive trauma are observed

If the physician successfully completes these tests, he/she will be considered trained and allowed to use the device on patients. For the first two patients, Dr. Watson will observe as a safety precaution. This is similar to other interventional training protocols such as GDC coils, stents, and arteriovenous malformation embolic agents.

10c. *Information on Cadavers*

Georgetown University Medical Center operates a cadaver donor program for the benefit of medical education and research. It is directed by Dr. Martin Dym, Professor and Chair of the Department of Cell Biology. The cadavers are used mainly for teaching gross anatomy to our first year medical students. In addition, cadavers are frequently made available to faculty from the various surgical specialties for the education of residents and fellows and for the surgeons to practice certain difficult procedures prior to surgery on a patient. Faculty from the Department of Radiology also have access to the cadavers for various research projects.

The cadavers are all donated to the Medical School and the utmost care is taken to treat the bodies with the greatest respect. The cadavers are stored in a modern morgue facility at the Medical School. A full-time Diener embalms the bodies and assists the students and faculty as required for teaching or research. Each semester, when all the studies requiring cadavers are completed, the remains are cremated by morgue personnel and buried in Mt Olivet cemetery, Washington, DC. A Georgetown University headstone honors the donors. A mass for the donors is held at our hospital chapel each year and many relatives of the donors along with close to 200 students attend.

In the protocol described here, the cadavers will be transported to the Radiology Interventional Suite in the hospital, which is directly connected to the Medical School. The studies in the Interventional Suite will only be done on weekends, evenings, and holidays, and will never be conducted during normal patient exam hours. The cadavers will be draped at all times when they are being transported and they will always remain under the direct supervision of a faculty member during the entire protocol.

11. Statistical Analysis Plan

The statistical analysis will be done by the biostatistician consulting on the project, Larry Muenz, PhD. His resume is included in the packet submitted to the Army HSRRB.

11a. *Introduction to the statistical text*
This is a two-phase, prospective study of a novel medical device. Phase 1 (cadaver study) is a single group pilot study and, while a power calculation appears below, phase 1 is primarily intended to gain experience in the use of the device and to estimate data features (e.g., standard deviation of the distance from needle tip to target) that are useful in the study's second phase. Phase 2 (human trial) is a moderate-size (n = 50 in each of two groups) randomized comparison of needle placement with and without the robotic placement device. The phase 1 primary outcome is binary: "success" or "failure" in placing a needle within 3 mm of the BB target. In phase 2 the primary outcome is the distance from needle to target, and the secondary outcome is the patient's self-reported pain relief.

Data from the 12 phase 1 patients and the first 20 patients in phase 2 (22 with the robotic device, 10 without it) will be used to estimate the standard deviations of the distance from needle to target. If these preliminary data suggest that the phase 2 study is over-powered, it will be curtailed and, if under-powered, it will be modestly enlarged to a maximum of 120 patients, not necessarily 60 and 60. However, the power calculation below is performed with n = 100 in a balanced design.

This section continues with calculations to relate power and detectable effect for both phases 1 and 2. Following some general remarks on data analysis, the section concludes with tests of the primary hypotheses for both phases.

11b. *Power and detectable effects for the validation and training phase*
An initial calculation examined the precision with which failure rates could be estimated using a

sample of 12 independent placements. A failure occurs when the needle tip is not within 3 mm of the metal BB. If there are zero observed failures in 12 placements, the 90% upper, one-sided, exact confidence bound for the true failure rate is 17.5%. The upper bound is 28.8% if one failure is observed, and 38.6% if two failures are observed. Thus, consistent with the preliminary nature of this study, a small number of failures in 12 placements yields a fairly large upper bound for the true failure rate. If zero failures were observed, a sample size of 45 would be needed to keep the 90%, one-sided upper bound for the true failure rate below 5%.

A second sample size and power calculation was done to examine the study's ability to distinguish between desirable and undesirable chances of failing to place the needle tip within 3 mm of the metal BB target. The calculation was performed using the clinical trial software STPLAN. The null hypothesis is that the proportion of 12 needle placements, assumed statistically independent, that are more than one 3 mm from the BB is a large, "undesirable" value while the alternative hypothesis is that the proportion of such unsuccessful placements is smaller (H_0: $p = p_0$; H_1: $p = p_1 < p_0$ where p_0 and p_1 are the undesirable and desirable proportions, respectively). For a range of undesirable proportions p_0 from 0.4 to 0.25, the calculation yields the desirable proportion p_1 that can be detected with type I error 5% and power 80%. The discrete, exact calculation produces a value of $p_1 = 0.069$ for p_0 in the range from .35 to 0.4 and a value of $p_1 = 0.018$ for p_0 from 0.25 to 0.3. For $p_0 \leq 0.2$, no value of p_1 can yield a test with type I error near 5%. Thus, in order to reject the null hypothesis of failure rates of 35-40%, or 25-30%, the true failure rates must be 7% and 2%, respectively. A larger study would, of course, be able to detect smaller differences between desirable and undesirable failure proportions.

11c. *Power and detectable effects for the human subjects phase*
The calculation here concerns two randomized groups of 50 subjects each, one group using the robotic placement device and one without it. The primary outcome is the distance between needle tip and arrow tip. Suppose that these distances are standardized so that each group's distribution has standard deviation 1. (The 12 subject pilot study will permit estimation of the two standard deviations although such estimates are highly variable.) A two-sample Student's t-test calculation, $n = 50$ per group, shows that effects of size 0.566 and 0.655 can be detected with power 80% and 90%, respectively, for two-sided tests with type I error 5%. These are considered moderate-to-large effects.

Pain relief, compared before and after needle placement, is a secondary outcome. We shift the focus here to a test of non-inferiority, testing the one-sided hypothesis that pain relief with the robotic device is, at worst, slightly less than pain relief without the device. In other words, we are testing the hypothesis that, in regard to pain relief, no harm is done by the robotic device. This is an example of an hypothesis of equivalence; "non-inferiority" is one-sided equivalence.

Let μ_N and μ_R denote the true (i.e., population) mean values of these two changes in pain scores for the non-robotic (N) and robotic (R) interventions, respectively. A more negative change (a smaller number) is desirable. For a specified δ, R is considered non-inferior to N if μ_R is no more than δ greater than μ_N. For example, we might use $\delta = 2$ points on the McGill-Melzack Present Pain Index (described in Section 9e). The non-inferiority study hypotheses are then

$$H_0: \mu_R - \mu_N \exists \delta \text{ and } H_1: \mu_R - \mu_N < \delta$$

Under the null hypothesis, H_0, the robotic intervention is markedly inferior while, under hypothesis H_1, R is not markedly inferior, as demonstrated by a sufficiently small one-sided, upper confidence bound for the difference $\mu_N - \mu_R$. The power of the test of non-inferiority is then

$$1-\beta = M\{(n/2)^{1/2}(\mu_R-\mu_N+\delta)/\sigma - z_\alpha) \text{for } \mu_R-\mu_N > -\delta$$

Until an estimate for σ is available from the study's first 32 patients (12 in phase 1 and 20 in phase 2) only the standardized effect $(\mu_R-\mu_N+\delta)/\sigma$ can be calculated. With 80% power, a one-sided test with type I error 10%, and two groups of size 50, this term is 0.427. (See Makuch and Simon [1978][2] to justify using 10% type I error.) So, if $\mu_R = \mu_N$, as usually assumed for non-inferiority sample size calculations, δ must exceed 0.427 σ or there will be insufficient power to show non-inferiority. For example, a five-point standard deviation of the McGill-Melzack score permits pain improvement with the robotic device to be as much as 2.1 points less than improvement without the device before considering the device to be inferior.

11d. *Data analysis for each study phase*

Analyses will be done with SAS software, version 8, primarily PROC FREQ, UNVARIATE, and GLM. P-values of 0.05 or less will be considered significant in two-sided tests, except for the phase 2 hypothesis of non-inferiority which is inherently one-sided. No multiple comparison corrections will be used. The primary analysis of phase 2 data uses an evaluable sample, with no missing outcomes. Should there be more than a few missing observations, a sensitivity analysis will compare the evaluable sample to an intention-to-treat sample that includes subjects with missing observations.

PHASE 1 (cadaver study) : Statistical analyses of these pilot data are informal, primarily intended to gain experience useful in phase 2. As the outcome is binary (needle tip further than 3 mm of BB target), the analysis estimates and forms an exact upper 90% confidence bound for this proportion of failures. An informal comparison will be made between the two soft tissue placements (facet block vs. nerve block); with n = 6 per type, sample sizes are insufficient for formal inference within the strata.

PHASE 2 (human trials) : Analysis of this randomized comparison is more elaborate than for phase 1. The data of the first 20 patients, combined with the 12 phase 1 patients, will be used to estimate the standard deviation of the distance from needle to target. This will be used in a two-sample non-inferiority power calculation, as outlined above, to determine if the sample size of 100 is adequate. As discussed above, based on this calculation, sample size will be maintained at 100, decreased, or slightly increased. In the unlikely event that the calculation implies the need for a large sample size increase, the study will be halted until the protocol can be amended.

Data analysis begins by validating the randomization; the groups are compared regarding type of placement, age, and other features potentially relevant to device performance. A linear regression model is used to test the study's primary hypothesis that smaller distances are attained from the target with the robotic device than without it. The regression model has the distance as the

[2] Makuch R, Simon R (1978). Sample size requirements for evaluating a conservative therapy. Cancer Treatment Reports, Vol. 62, 1037-1040.

dependent variable, perhaps requiring transformation. As independent variables we will include method of placement (robotic or not), and patient's age. Interactions of placement method and other variables may also be needed in which case it may be that the robotic device is not uniformly superior to its absence in all circumstances.

Pain relief is also compared by linear regression, with change from pre- to post-placement as the dependent variable, again possibly requiring transformation. Now, however, the hypothesis of non-inferiority is tested by using the regression to form a one-sided upper 90% confidence bound for the adjusted difference in pain relief "device minus no-device." The robotic device is not inferior to its absence if this bound does not exceed the specified δ change in McGill-Melzack pain score. In that case, we infer that the robotic device does no harm if the true improvement in pain without the device is no more than δ greater than the true improvement with the device. This model may also contain interactions of placement method and other variables, again implying a conclusion that varies by patient feature.

MISSING DATA: It may be that, with or without the device, needle placement is not performed in some randomized subjects. If this occurs randomly, sample size and power for effect detection are both decreased. However, non-random loss is more problematic as the remaining subjects may yield biased conclusions. An initial check for this compares baseline features of those with and without missing outcomes. If there are more than a few subjects with missing observations, "multiple imputation with non-ignorable missingness" will be used to estimate the missing values of the needle-to-target distance and the change in pain scores. This analysis is repeated a few (e.g., 3-10) times, yielding a single estimate of the true outcome, and a correct variance estimate that does not naively assume that imputed values are real data.

12. Discuss any unusual procedures.

No unusual procedures are planned, as the procedures mentioned here are currently being done at Georgetown. The only difference is that a robotic device will be used to help place and manipulate the instruments.

13. Indicate what you consider to be the risks to the patient and indicate the precautions to be taken to minimize or eliminate these risks.

While the investigators will do everything possible to minimize or eliminate risks, it is impossible to predict in advance everything that might happen since this robotic device has not been used previously for spinal procedures. The robotic device is locked into position and the instrument path will be continuously monitored. The robotic device is electrically shielded and conforms to all standard laboratory requirements. The robotic device will be inspected and approved by GUMC Clinical Engineering. The physician will remain in direct control of the robotic device at all times, and can discontinue its use at any time. The risks and discomforts should be no different than the usual risks and discomforts associated with these procedures.

It should be noted that the benefits to the patient of using the robotic device are unknown and there may be no direct benefit to any individual subject participating in the study.

14. Informed consent process

Informed consent will be obtained for all patients participating in the study using the consent form approved by the Institutional Review Board at Georgetown University and the U.S. Army Human Subjects Research Review Board. Before the procedure is carried out, a member of the medical staff will explain the procedure including the risks and benefits and allow the patient to review the consent form as well as answer any questions. A brief history and physical will be included as part of the process. The IRB consent form will be stored in the Interventional Radiology Department in a locked storage container.

15. Reporting of serious and unexpected adverse events

Serious and unexpected adverse experiences will be immediately reported by telephone to the USAMRMC Deputy Chief of Staff for Regulatory Compliance and Quality [(301) 619-2165, during non-duty hours call (301) 619-2165 **and** send information by Fax to (301) 619-7803. A written report will follow the initial telephone call within three working days and will be addressed to: U.S. Army Medical Research and Materiel Command, ATTN: MCMR-RCQ-HR, 504 Scott Street, Fort Detrick, MD, 21702-5012.

16. Volunteer Registry Data Base Requirements

It is the policy of the U.S. Army Medical Research and Materiel Command (USAMRMC) that data sheets are to be completed on all volunteers participating in research for entry into this Command's Volunteer Registry Data Base. The information to be entered into this confidential data base includes your name, address, Social Security number, study name and dates. The intent of the data base is two-fold: first, to readily answer questions concerning an individual's participation in research sponsored by the USAMRMC; and second, to ensure that the USAMRMC can exercise its obligation to ensure research volunteers are adequately warned of risks and to provide new information as it becomes available. This information will be stored at USAMRMC for a minimum of 75 years.

17. Medical Monitor

The medical monitor for this project is: Patrick Oliverio, MD, Neuroradiology, Department of Radiology, Georgetown University Medical Center. Telephone: (202) 687-1638. As required by Army human subjects regulations, the medical monitor is not associated with this protocol, is capable of providing medical care to research subjects for conditions that may arise during the course of the study, and will monitor the subjects during the course of the study.

18. Disposition of Data

Research data and related records for this project will be stored at the hospital in the office of our research associate, David Lindisch, RT. This is a private locked office and only study personnel are allowed access to this office. The data will also be stored on a Windows NT personal

computer in this office. Access to this computer is password protected. The data will be stored for up to two years after the closure of the study.

Since this computer is connected to the hospital network (which in turn provides Internet connectivity) in order to access the hospital database, steps will be taken to minimize the possibility of external computer attacks. The personal firewall product, BlackICE defender from Network ICE (www.netice.com), will be used to safeguard against computer attacks. This product has been highly recommended by security experts and one of the co-investigators has used this product with great success for the last year.

19. Modification of the Protocol

Any modifications to the protocol will be first reviewed and approved by the Georgetown Institutional Review Board (IRB) and then the Army Human Subjects Research Review Board (HSRRB) before implementation. The nature of the modification will determine the type and level of the review.

20. Describe any special equipment that will be used for this research project.

Special equipment planned for this project is the robotic device developed collaboratively by Georgetown University and Johns Hopkins Medical Institutions. This device will be modified for this research project as described in Section 9, the Plan of Study.

21. Will any additional care be needed for patients admitted for this project?

No additional care will be required.

22. Indicate any proposed compensation for participation in cash or in kind.

No compensation or other payments will be made..

23. Responsibilities of Principal Investigator to the Surgeon General

The material below is clause 13.01 from the U.S. Army Human Subjects Protection Division and is incorporated here for reference. The principal investigator is responsible to:

1. To promptly report changes or unanticipated problems in a research activity. Normally, changes may not be initiated without TSG approval, except where necessary to eliminate apparent immediate hazards to the human subject or others.

2. To immediately report by telephone (DSN 343-2165 or 301-619-2165; during non-duty hours call DSN 343-2165 and send information by facsimile to DSN 343-7803 or 301-619-7803) serious or unexpected adverse experiences which occurs to the human subject or others.

3. To promptly report any change of investigators.

4. To prepare, at a minimum, an annual progress report or final report in accordance with Title 21, Code of Federal Regulations, Part 312.33.

5. To immediately report to HSPD knowledge of a pending compliance investigation by the Food and Drug Administration (FDA) or other outside governmental agency concerning clinical investigation or research.

24. List of Appendices

Appendix A: Urine collection procedure
Appendix B: Statement of work for subcontract to Johns Hopkins to build robotic device
Appendix C: Article describing robotic system by developers at Johns Hopkins
Appendix D: Nerve and facet joint injection (instructions to patients from Dr. Watson)
Appendix E: Georgetown consent for surgery, anesthetics, and other medical services
Appendix F. Short form McGill pain questionnaire (McGill-Melzack)

25. Signature Page

I certify that the information furnished concerning the procedures to be taken for the protection of human subjects is correct. I will seek and obtain prior approval for any substantive modification in the protocol and will report promptly any unexpected otherwise significant adverse effects encountered in the course of this study.

I certify that all individuals named as consultants or co-investigators have agreed to participate in this study.

_____ Date _____

Vance Watson, M.D.
Principal Investigator

1) Department chairman:

Approved _____ Disapproved _____ Date _____

_____

Michael Pentecost, M.D.
Chairman, Department of Radiology

2) Institutional Review Board:

Approved _____ Disapproved _____ Date _____

_____

Chairman, Institutional Review Board